D4.4

EUR3KA R3 Cognitive Digital Twin Services – Final release

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016175

D4.4 EUR3KA R3 Cognitive Digital Twin Services – Final release

Work Package:	WP4
Lead partner:	ENG
Author(s):	Angelo Marguglio (ENG), Gabriele De Luca (ENG), Mattia Giuseppe Marzano (ENG)
Due date:	30/11/2022
Deliverable Type:	Report
Version number:	1.0 **Status:** Final

Project Number:	101016175 **Project Acronym:** Eur3ka
Project Title:	*EUropean Vital Medical Supplies and Equipment Resilient and Reliable Repurposing Manufacturing as a Service NetworK for Fast PAndemic Reaction*
Start date:	December 1st, 2020
Duration:	27 months
Call identifier:	H2020-SC1-PHE-CORONAVIRUS-2020-2-NMBP
Topic:	SC1-PHE-CORONAVIRUS-2020-2A Repurposing of manufacturing for vital medical supplies and equipment.
Instrument:	IA

Dissemination Level	
PU: Public	X
PP: Restricted to other programme participants (including the Commission)	
RE: Restricted to a group specified by the consortium (including the Commission)	
CO: Confidential, only for members of the consortium (including the Commission)	

Revision History

Revision	Date	Who	Description
0.1	16/03/2022	ENG	Table of contents, Partner Responsibilities
0.2	19/05/2022	ENG	Collecting Contributes
0.3	14/11/2022	ENG	ToC Refinements
0.4	24/11/2022	ENG/INNO	ToC Restructuring
0.5	22/12/2022	ENG	Preparation for internal review
0.6	28/12/2022	ENG	Refinements after internal review
1.0	29/12/2022	ENG	Final coordinator review before submission

Quality Control

Role	Date	Who	Approved/Comment
Internal review	23/12/2022	VIS	Approved
Internal review	29/12/2022	ENG	Approved

Disclaimer

Executive Summary

COVID-19 pandemic has exponentially accelerated the adoption of digital technologies in the manufacturing domain. Only a few were looking at Industry 4.0 to transform their businesses into customer-centric models. The companies had to accelerate digital technologies adoption during COVID-19 to avoid losing their business opportunities, trying to gain momentum rapidly in terms of manufacturing production going to meet the major shift in customer demands, challenging planning systems, and operational cost optimization. The Eur3ka project aims to build and validate a plug and response platform that will enable manufacturers to respond to the challenges arising from the COVID-19 healthcare crises and related future events that could disrupt production operations. All the consortium partners were involved in the development of a pool of services. This document describes in three categories (Pre-crisis Assessment, Pre-crisis Preparation and Crisis Response) the services implemented to satisfy the experiments needs to be mapped toward the Eur3ka Reference Architecture defined in D2.1, representing the main pillars of the 4 Grand Scenarios introduced in D3.1.

A significant part of the deliverable is devoted to describe the outcomes of WP4 tasks, the technical enablers defined in WP3 are now completed and support the Eur3ka network to satisfy experiments needs as required in WP5. The focus is put on the cross-sectorial supply network, ensuring the resilience and the dynamic configuration of production capabilities and a way to guarantee the production continuity respecting at the same time security needs and finally the services useful to obtain flexible manufacturing automation and products.

Table of Contents

List of figures

List of Tables

Definitions and acronyms

AI	Artificial Intelligence
AAS	Asset Administration Shell
AM	Additive Manufacturing
AMN	Additive Manufacturing Network
API	Application Programming Interface
AWS	Amazon Web Services
CA	Certificate authority
CaaS	Certificate as a Service
CAD	Computer-Aided Design
CCE/PPE	Certified Conformity European/ Personal protective equipment
CDT	Cognitive Digital Twin
CI/CD	Continuous Integration/Continuous Delivery
CSR	Certificate Signing Request
DAPS	Dynamic Attribute Provisioning Service
DAT	Dynamic Attribute Token
DC	Data Consumer
DNS	Domain Name System
DP	Data Provider
DSC	Data Space Connector
DBMS	Database Management System
EDC	Eclipse Dataspace Connector
GD&T	Geometric Dimensioning and Tolerancing
GFX	Geometric Feature Extraction
GUI	Graphical User Interface
IDS	International Data Spaces
IoT	Internet of Things
IP	Internet Protocol
IRI	Internationalized Resource Identifier
ISO	International Standards Organization
JSON	JavaScript Object Notation
JWT	JSON Web Tokens
LTS	Long Term Support
MPFQ	Material (M), Production Process (P), Product Functions/Features (F), Product Quality (Q)
PAAS	Platform as a Service
P2P	Peer 2 Peer
PKI	Public Key Infrastructure
QC	Quality Control
QIF	Quality Information Framework
QMS	Quality Management System
RA	Reference Architecture
REST	Representational state transfer
ROI	Region of Interest
RPS	Reference Point System
SFW	Smart Factory Web

SLA	Service Level Agreement
SM	Subtractive Manufacturing
SMMA	Smart Matching and Mediation Application
UI	User Interface
WP	Work Package
ZDM	Zero Defect Manufacturing

1 Introduction

1.1 Scope and Purpose

In a disruptive marketplace, the ability to orchestrate the supply chain will be an essential competitive differentiator and a key capability for a best-in-class supply chain. Lockdowns, travel restrictions, demand evaporated in some categories and skyrocketed in others, the transition to remote working, any other kind of blocking activities can disrupt the economy, raising at the same time the need of organizing and integrating information from disparate parts of the organization and then making informed, integrated to take timely decisions. The priority for most companies is to make their supply chains far more flexible, agile, and resilient. That's what Eur3ka will boost: the agility, flexibility, and resilience of the manufactory chains for any kind of unforeseen future.

The present deliverable describes the services developed thanks to the technical enablers defined in WP3 and grouped by pre-crisis assessment, pre-crisis preparation, and crisis response. A direct link with the Reference Architecture (RA) is defined, mapping among its blocks and the services currently developed. This document depicts not only the technical enablers and their relationship with the RA but also a key concept of Industry 4.0, the Cognitive Digital Twin (CDT), a promising evolution of the current Digital Twin towards a more intelligent, comprehensive, and complete lifecycle representation of complex systems.

1.2 Structure of the document

The deliverable is structured in three main categories as follows:

- **Section 2 Pre-crisis Assessment** defines the services to repurpose the infrastructures, validating the processes and risks that can occur in supply chains.
- **Section 3 Pre-crisis Preparation** introduces the concepts of production continuity services in terms of advanced AI-powered data-driven decision support services for risk and the social distancing virtual assessment for virtual repurposing and commissioning. The services for flexible manufacturing automation and products will be discussed.
- **Section 4 Crisis Response** describes the services oriented to address the crisis response, such as smart matching & mediation services, a smart search engine to match medical product manufacturing specifications, and Eur3ka manufacturing network resources such as the quality control tools and the catalogue containing the resources.

The technical enablers developed in the Eur3ka project are classified and mapped in the abovementioned categories, creating a direct link with the reference architecture building blocks defined in D2.1 with the scope of satisfying experiments needs as required in WP5.

2 Pre-crisis Assessment

2.1 Production Repurposing & Resiliency Maturity Assessment Services

In order to build a holistic understanding of the repurposing manufacturing phenomenon, we have conducted several case studies to obtain data on the phenomenon. The data was collected from the partners involved in Eur3ka Project and beyond. The structure of the Eur3ka Project and collaborations with partners tremendously helped to collect rich empirical data on the emerging phenomenon of manufacturing repurposing. The details of the case studies are available in the Table below.

Table 1 - List of Eur3ka Case Studies

Case studies	business sector	Product	Technology	Region
A	Research and Technology	Visor holders for magnifying glass	Additive Manufacturing	Denmark
B	Sanitary systems and parts manufacturer	Face shields	Injection Moulding	Switzerland
C	Technical articles	Face masks and medical gowns	Digital Dataspace	Italy
D	Textile	Face masks and medical gowns	None	India
E	Technical textiles	Face masks and medical gowns	Digital marketing	Netherlands
F	Research and Technology	Face masks	Nanotechnology	Malaysia
G	Research and Technology	Nanotechnology air filtration system	Nanotechnology	Malaysia
H	Mechatronics	Respiratory Equipment	Modular Manufacturing	Netherlands
I	Textile	FPP2 Mouth Masks	Filtration	Netherlands

From our case studies, we have extracted rich information on the repurposing manufacturing which occurred during the pandemic. Through this data collection, we systematically analysed the data to extract the important building blocks as a foundation for the maturity

assessment. From the semi-structure interviews conducted with industry experts, we simplify the system's complexity through two causal loop diagrams.

At the macro level, manufacturing repurposing is seen to be reinforced by the pandemic and enablers such as third-party funding, governmental funding, and also emergency regulations, which contributed positively to the success of manufacturing repurposing. Moreover, community efforts served as a balancing loop for manufacturing repurposing providing support to manufacturing repurposing activities.

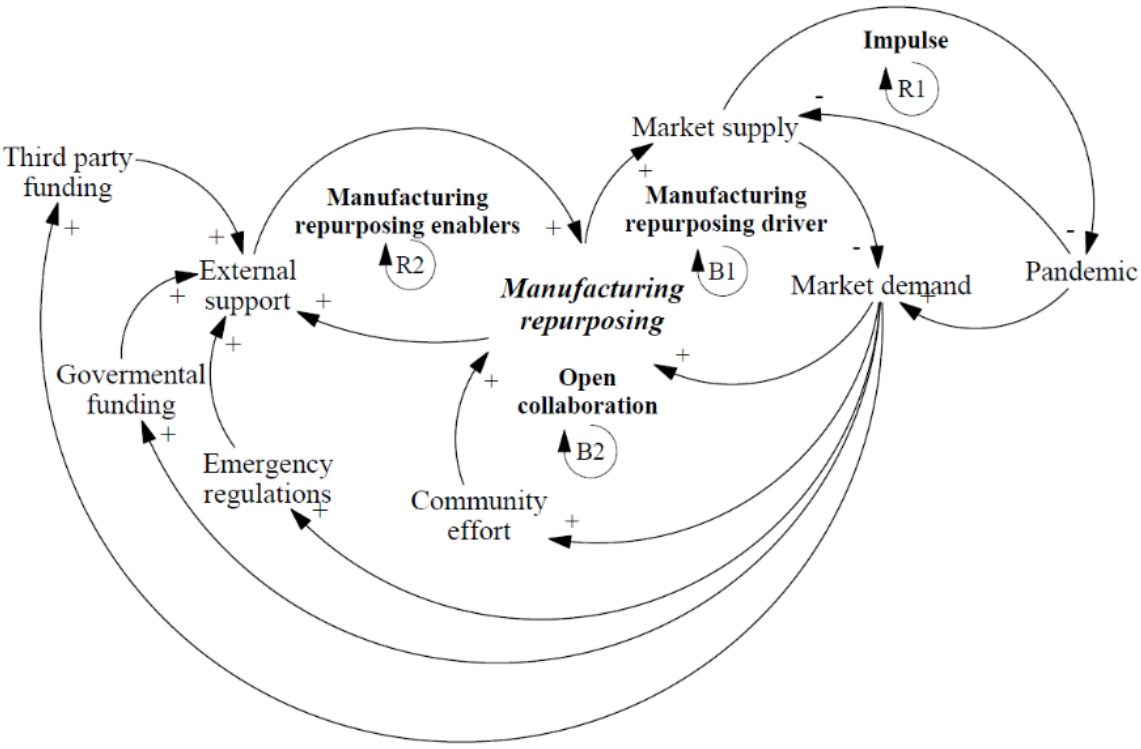

Figure 1 - Framework of manufacturing repurposing at the macro- level

At the micro level, the core enablers were the product and process capabilities of the firm. Some firms are seen to have supply chain capabilities, while others have know-how about the product. In order to systematically validate the current framework, we designed a maturity assessment model.

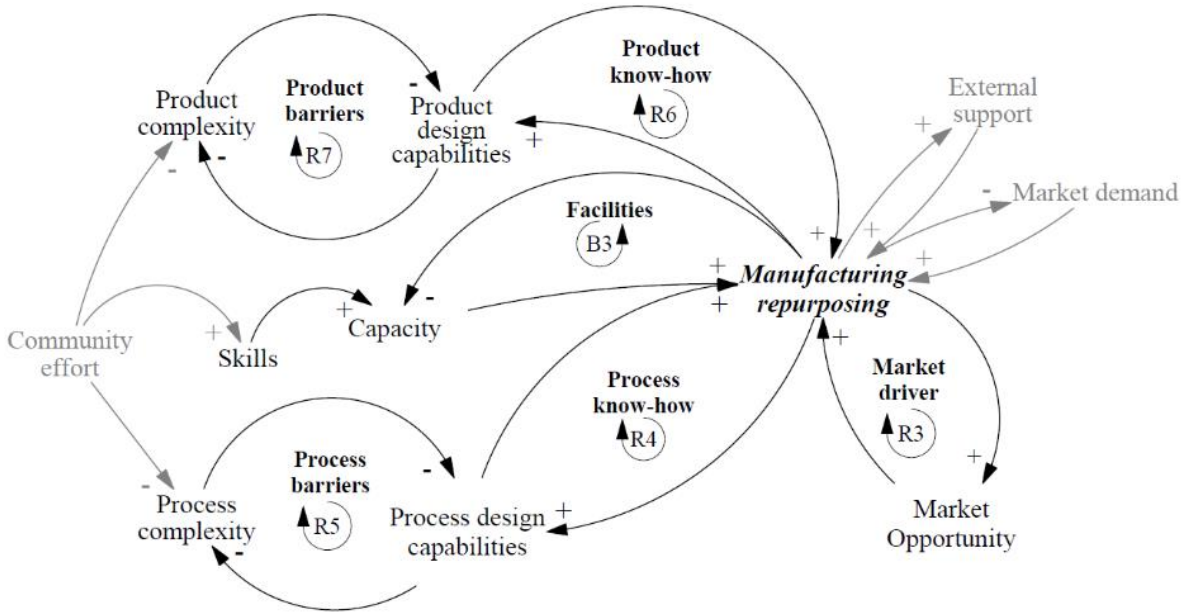

Figure 2 - Framework of manufacturing repurposing at the micro-level

The maturity assessment is classified into four broad categories (see Figure 3):

- external factors
- organizational factors
- product-related factors
- supply chain-related factors.

The *external* factors deal with the role of external funding, governmental support, regulations, and community efforts. The *organizational* factors are concerned with the capabilities of existing physical facilities and equipment, internal know-how (such as agile product development, engineering, etc.), the flexibility of production lines (such as modularly, flexible layout, etc.), dependence on external know-how (such as consulting from other organization and healthcare institutes), and the flexibility of developing new organizational routines (such as new organizational charts). The *product*-related factor mainly involves the level of product complexity. Finally, the *supply chain*-related factors include the demand in the market (and changes in demand) and the raw material availability (and volatility of supply).

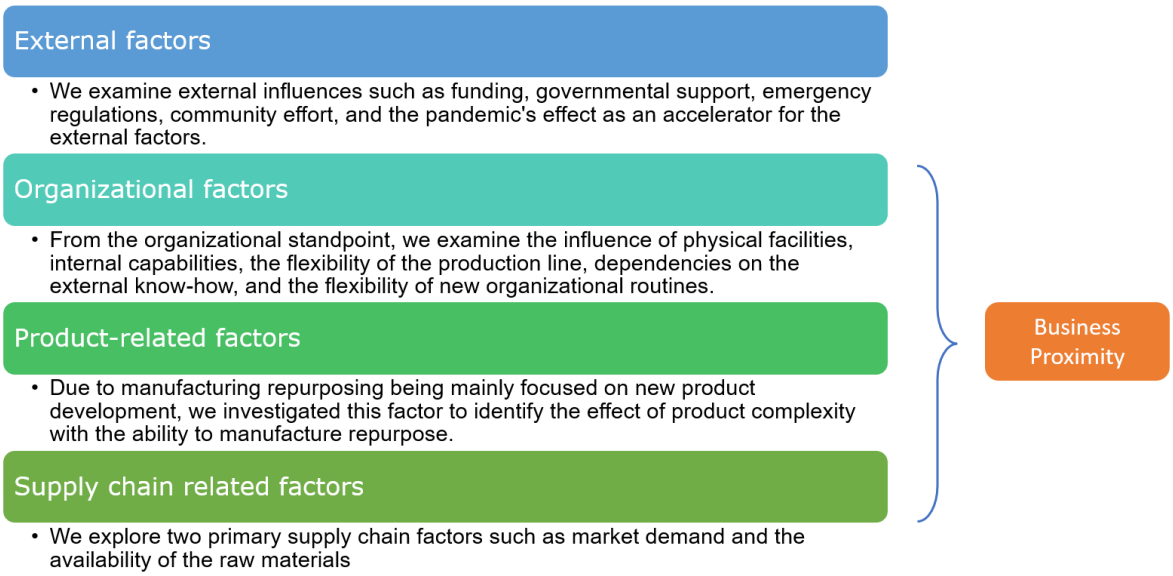

Figure 3 - Business Proximity

From the evaluation of the three factors: organizational, product, and supply chain, we can determine the ***business proximity*** of the firm to the product of manufacture. We introduce this term as an indicator of the closeness of the firm to the product of manufacture to allow organizations to understand the level of change required to manufacture the new product.

For example, our case studies found that companies that manufactured sanitizers primarily stemmed from the alcohol manufacturing or distillery industry. This is due to the high business proximity to the new product of manufacture, which acted as an enabler for organizations.

2.2 Production Repurposing Data Infrastructure Registry

2.2.1 IDS Core infrastructure schema and essential components description

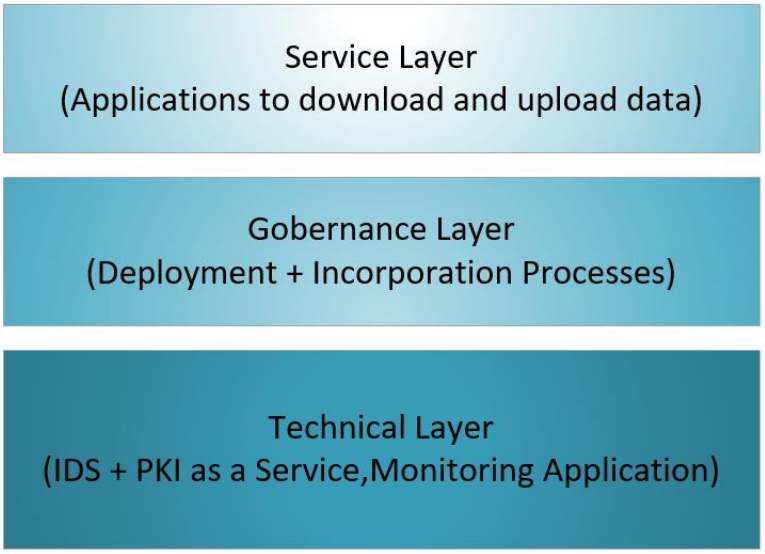

Figure 4 - Layers of the IDS infrastructure

This section describes the development of a validated and scalable IDS (International Data Spaces) compliance infrastructure ready to be safely deployed and operated within strict timing constrains to implement a data-sharing process of 3D printable models.

Figure 4 shows the three layers of the development carried out.

2.2.1.1 DEVELOPMENT LAYER DISTRIBUTION

The development has been carried out in three different layers: the technical layer (that englobes all technical development and integration), the governance layer (that englobes all requirements and deployment guidelines to operate the Data Space), and the service layer (that englobes applications and tools to help end users to manage and download data, track transactions, etc.).

LAYER 1. TECHNICAL LAYER

It comprises the IDS core Infrastructure offered as a service.

The development performed integrates the following technical components in Figure 5:

- Block 1: Complete IDS core infrastructure offered as a service that can be automatically deployed in a cloud infrastructure. The package provided includes all IDS core components necessary to deploy a Data Space.
    - This infrastructure can be automatically deployed and configured in 4 hours.

- Block 2: A “PKI as a Service” ready to provide Digital Certificates to providers and consumers of the Data Space. For this technical enabler, the CA’s will be distributed by ATOS.
    - This component can be installed, and it is ready to use in 4 hours.
- Block 3: An Application to monitor data transfer within the Data Space.
    - This application can be installed and configured in 2 hours.

The next picture shows the different components.

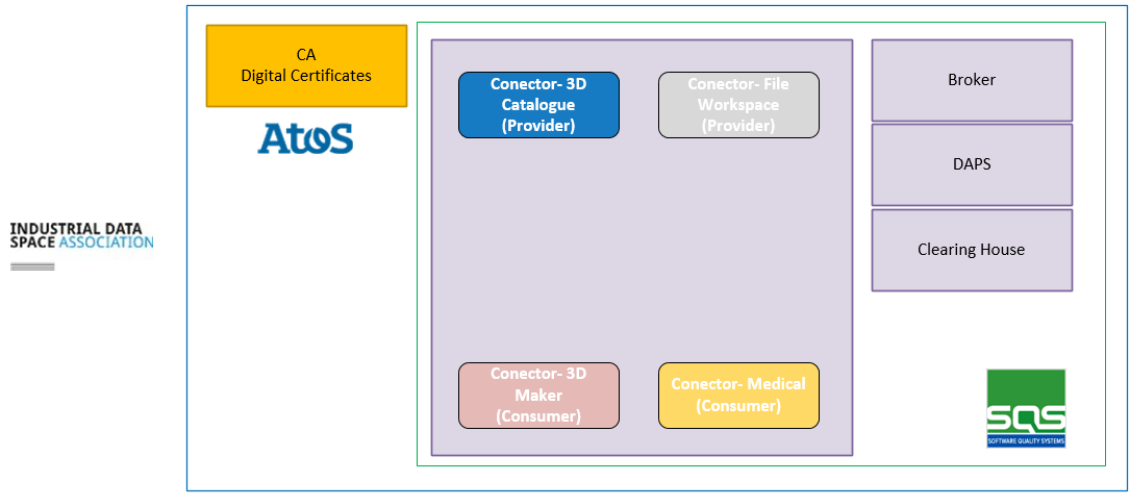

Figure 5 - Components of the Technical Layer

LAYER 2: GOVERNANCE LAYER

It comprises the services required to deploy and operate the Data Space.

It covers two processes:

- Deployment process: The entire infrastructure can be deployed and configured in 8 hours following the deployment process shown in Figure 6.

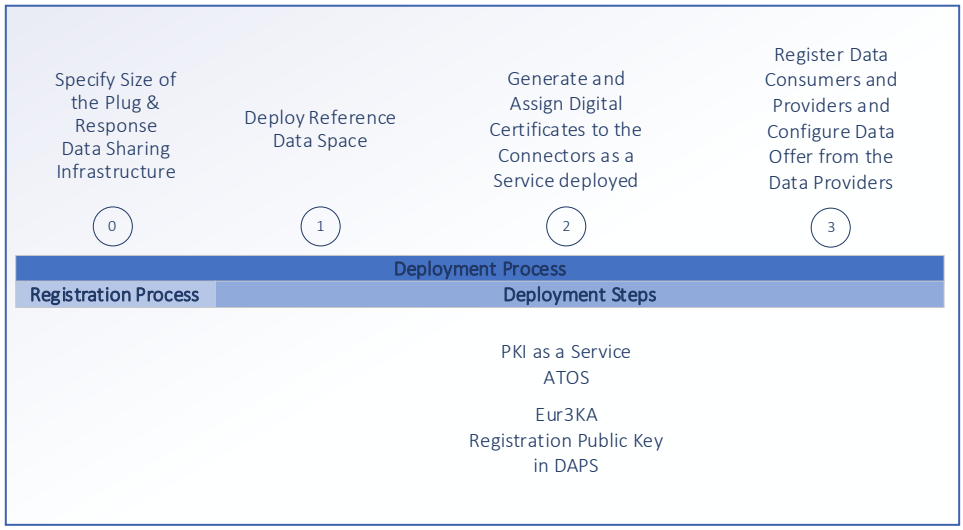

Figure 6 - Deployment Process

- Incorporation Process: Figure 7, presents the model prepared to manage the incorporation of new connectors and users in the Data Space.

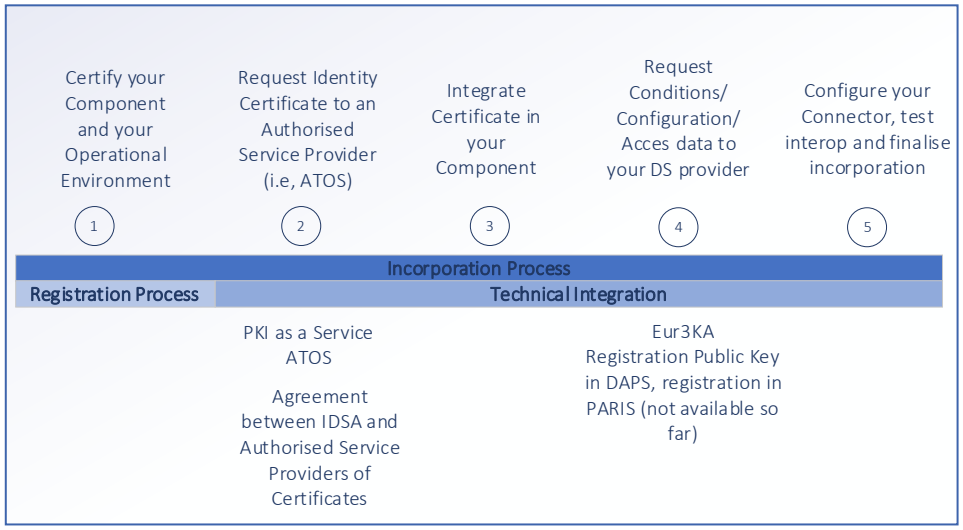

Figure 7 - Incorporation Process

LAYER 3: SERVICE LAYER

It comprises services to facilitate the transfer of data. In this case, 3D printable models.

- Applications to facilitate the data sharing of 3D Models to providers and consumers. These applications are distributed to data consumers and providers if needed.

2.2.1.1 TECHNICAL LAYER COMPONENTS

The development *Block 1* is composed of: DAPS (Dynamic Attribute Provisioning Service), BROKER, CLEARING HOUSE, and 4 DSCs (Data Space Connector).

The *Block 2* is the PKI As a Service. In this case, ATOS Certificates will be used to verify all the components' identities.

The development *Block 3* is a monitoring service. This is implemented as an end-user application that shows information about the transactions based on the logs provided by the CLEARING HOUSE component.

2.2.1.1.1 DAPS (Dynamic Attribute Provisioning Service)

IDS connectors request a digitally signed JSON web token (JWT) from a central IDS component called Dynamic Attribute Provisioning Service (DAPS) in order to authenticate themselves. Without these DAPS tokens (called DATs), no connector can participate in the IDS ecosystem.

DAPS v1.6.0 is being used for SQS Infrastructure.

2.2.1.1.2 MDB (Metadata Broker)

This Metadata Broker is a registry for IDS Connector self-description documents. This registry can be consulted by any of the DSC connectors in the infrastructure to see how the dataspace structure looks like and to get some information (such as endpoints or data catalogues from all the providers) used for data exchange. Metadata Broker is still actively maintained by Fraunhofer IAIS.

MDB v5.0.0 is being used for SQS Infrastructure.

2.2.1.1.3 CLEARING HOUSE

The IDS Clearing House acts as an intermediary in the IDS ecosystem. All IDS Connectors may log information in the Clearing House to support any process that requires an auditable logging mechanism. This includes e.g., the following processes in the IDS:

- Data sharing between a Data Provider (DP) and a Data Consumer (DC)
- Data usage according to Usage Contracts or Data Usage Policies

All information from the clearing house can be retrieved to determine the good usage of the dataspace and the compliance between consumers and providers (DSC connectors) and can be used as proof in case of malicious use of that information.

This component is under continuous development, so the version will vary between the processes.

2.2.1.1.4 DSC (Dataspace Connector)

The Dataspace Connector is an IDS connector that Sovity is currently maintaining. The Dataspace Connector uses the recent IDS Information Model version and the IDS Messaging Services for message handling with other IDS components. For managing datasets by means of their metadata as IDS resources, the Dataspace Connector provides a REST API. After an initial registration, IDS resources are persisted to an internal or external database of the connector. External data sources can be connected via REST endpoints, allowing the Dataspace Connector to act as an intermediary between the IDS data ecosystem and the actual data source.

DSC v7.1.0 is being used for SQS Infrastructure.

In the basic deployment, 4 DSC connectors are automatically installed. The addition of new connectors can be done in 1 hour.

2.2.1.1.5 PKI as a Service

In order to verify all the components inside the Data Space, the use of X.509 certifications is needed. ATOS will provide this functionality as a service to simplify the process of getting and managing these certificates. ATOS web portal can be used to generate new certificates and access previously generated certificates. In this way, this process is automated and only requires access to the web portal (using credentials generated by administrators to the partners).

2.2.1.1.6 Monitoring Service

SQS has developed a desktop application to track the transactions made inside the Data Space. This application graphically shows all the logs stored at the CLEARING HOUSE component to have a quick global vision of all the transactions and data downloads. The application allows exporting all the logs to a CSV file to be saved locally by the administrator of the Data Space. This application is under continuous development, so the version will be varied during the process.

2.2.1.2 COMPONENTS OF THE GOVERNANCE LAYER

This layer englobes all the procedures and specifications needed to deploy the Data Space and modify or add new connectors to an existing Data Space.

2.2.1.2.1 DEPLOYMENT PROCESS

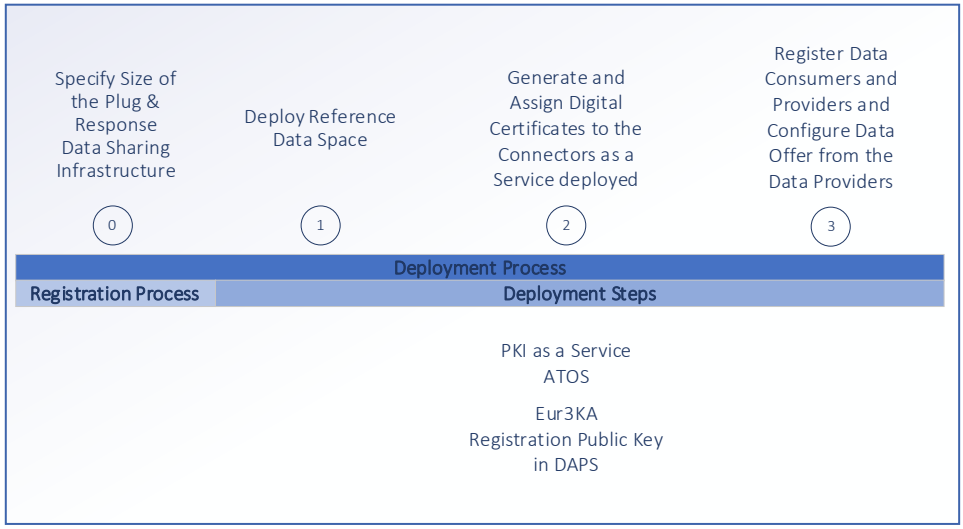

Figure 8 - Deployment process (2)

Below is reported a guide for the deployment following the deployment process represented in Figure 8.

STEP 0: Specify the Size of the Plug & Response Data Sharing Infrastructure

Requester: Participant (in our case, Suppliers, and Consumers) Responsible: IDSA

This previous-to-first step is needed to size the Data Space infrastructure and adjust the topology based on some factors.

- Data Providers and Data Consumers

- CaaS to be deployed in a first stage
- Volume and Type of 3D Models to be shared

Having all this information the Data Space deployment is ready to start.

STEP 1: Deploy Reference Data Space

The Data Space is given to the consumer packed as a GitHub repository. This way is easier to maintain and adapt to customer requirements.

The **hardware** minimum requirements to deploy the Data Space are:

- 4 GB RAM (however 8GB RAM is recommended)
- 50 GB storage
- It is recommended to use a 64bit quad core processor to provide enough processing power for all docker containers.

If more components are included in the Data Space or a huge amount of data is uploaded, it is possible to run out of disk free space. In these cases, it is recommended to provide more free disk storage.

The **software** requirements for the successful deployment:

- OS: Ubuntu 20.04.1 LTS
- Docker: 20.10.7
- Docker-compose: 1.27.4

For the deployment is recommended to use a virtual machine located on a server or cloud service. Preserve the public id of this machine to be used during the deployment process.

The Data Space comes preconfigured, so the deployment process is almost automated. The steps to completely deploy it are the following (all commands have to be used on the target machine for the deployment):

First, verify your ubuntu version:

```
lsb_release -a
```

The output should be similar to this:

```
No LSB modules are available.
Distributor ID: Ubuntu
Description:    Ubuntu 20.04 LTS
Release:        20.04
Codename:       focal
```

Then update your system with:

```
sudo apt-get update
sudo apt-get upgrade
```

Install docker and docker-compose:

```
sudo apt-get install docker
sudo apt-get install docker-compose
```

Verify installation with:

```
docker version
```

The output should look similar to:

```
Client:
 Version:           20.10.7
 API version:       1.41
 Go version:        go1.13.8
 Git commit:        20.10.7-0ubuntu5~20.04.2
 Built:             Mon Nov  1 00:34:17 2021
 OS/Arch:           linux/amd64
 Context:           default
 Experimental:      true
```

```
docker-compose version
```

The output should look similar to:

```
docker-compose version 1.27.4, build unknown
docker-py version: 4.3.1
CPython version: 3.8.10
OpenSSL version: OpenSSL 1.1.1f  31 Mar 2020
```

If your docker-compose version is not the required one, execute the following commands.

```
sudo apt-get install curl

sudo curl -L "https://github.com/docker/compose/releases/download/1.27.4/docker-compose-$(uname -s)-$(uname -m)" -o /usr/local/bin/docker-compose

sudo chmod +x /usr/local/bin/docker-compose
```

Download the repository to your local environment.

```
sudo apt install git

git clone “yourlink.git”
```

Move to the downloaded directory and execute the docker-compose.yml script.

```
cd IDS-testbed

docker-compose up
```

If you face problems with docker or user rights, execute the following commands and log out and back so that your group membership is re-evaluated.

```
sudo groupadd docker

sudo usermod -aG docker $USER

# Where $USER is obtained by executing in the terminal the command `whoami`

# Log out and log back in so that your group membership is re-evaluated.
```

Re-execute the docker-compose.yml script.

Now we will check the main containers (DAPS, DSC, and MDB). The components that are part of the Data Space can be reached at the URLs mentioned below:

- DAPS: Can be reached at https://localhost:443
- Connectors: Can be reached at https://localhost:8080 and so on (the only part that changes are the port. It will be incremented for each connector, so the next one is 8081, the next 8082, and so on).
- Broker: Can be reached at https://localhost:444

If all these steps are followed correctly, the Data Space is deployed. The next step is the CA generation and configuration.

STEP 2: Generate and Assign Digital Certificates to the Connectors as a Service deployed

The first step is to generate the private key and CSR. To do this, execute the following commands:

1. Generate the private key:

```
openssl genrsa -out server.key 2048
```

2. Fill the “server_cert.cnf” file parameters:

```
[req]
distinguished_name = req_distinguished_name
req_extensions = req_ext
prompt = no

[req_distinguished_name]
C = {Your Country}
ST = {Your state}
L = {Locality}
O = {Organization Name}
OU = {organization Unit Name}
CN = {Common Name}
[req_ext]
subjectAltName = @alt_names

[alt_names]
IP.1 = 127.0.0.1
IP.2 = {Enter here the IP of the connector}
DNS.1 = localhost
DNS.2 = {Enter here the DNS of your connector}
```

Note: please ensure that the DNS and IP of your component are correctly defined in the CSR. You can use KeyStore Explorer to check it.

3. Generate the CSR

```
openssl req -new -key server.key -out server.csr -config server_cert.cnf
```

4. Example configuration:

```
 [req]
distinguished_name = req_distinguished_name
req_extensions = req_ext
prompt = no
[req_distinguished_name]
C   = ES
ST  = Bizkaia
L   = Bilbao
O   = SQS
OU  = SQS Testlab
CN  = connectora
[req_ext]
subjectAltName = @alt_names
[alt_names]
IP.1 = 127.0.0.1
IP.2 = 14.134.214.24
DNS.1 = localhost
DNS.2 = connectora
```

Once you have the CSR you can go to the next part, and generate the certificate itself.

To generate certificates, we are going to use the PKI web portal from ATOS accessible through https://portal-test.pki.atos.net/AtosPKI/AtosPKILogin.html?tenant=StandardSSL.

The steps to generate the certificates are the following:

Go to the section Request certificate in the Server Center, read the ‘Certificate Practice Statement’ and ‘Subscriber Agreement’ carefully and get familiar with your obligations, regarding the Atos Trustcenter certificates.

Once you have read and agreed to the documents, check the ‘I accept’ checkbox and click on the ‘next’ button.

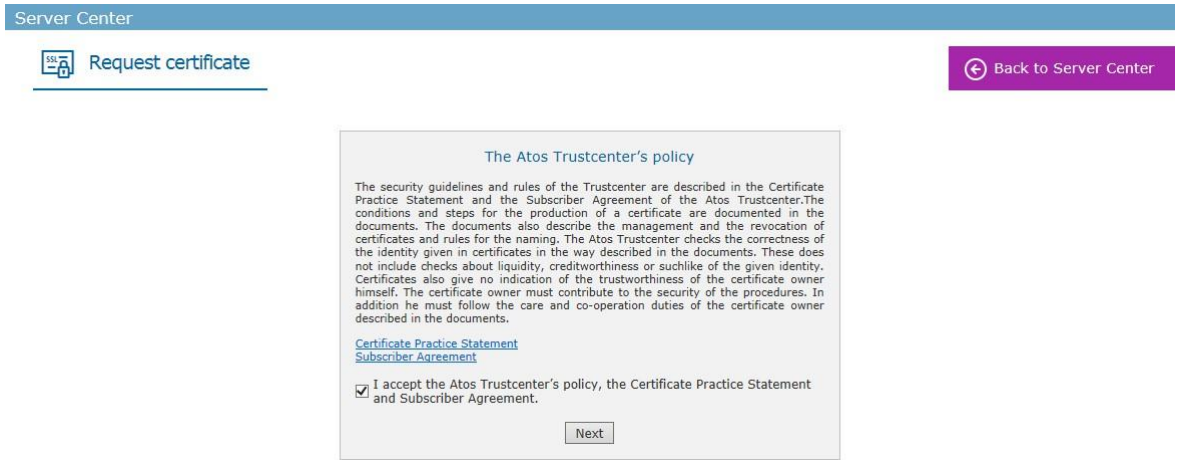

Figure 9 - Visualization of the Atos Trustcenter´s policy

On the next page, choose your company and group:

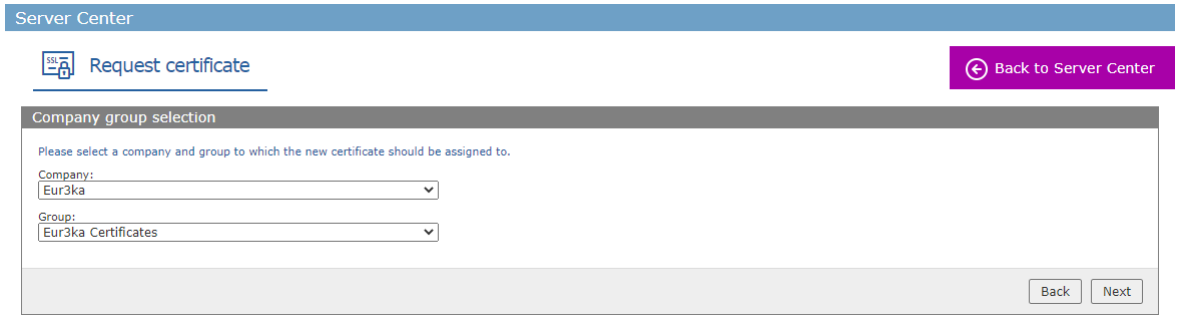

Figure 10 - Visualization of the company group selection

On the next page, choose the product and the runtime:

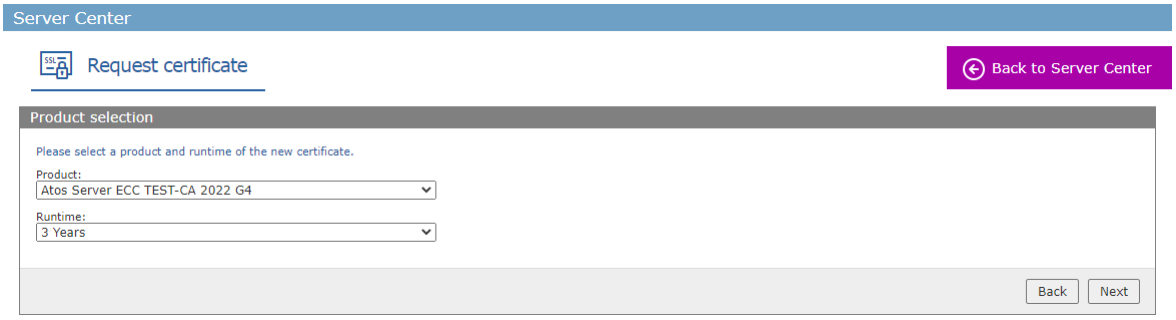

Figure 11 - Visualization of the product selection

On the next page, please enter the CSR, which you have generated and click on next:

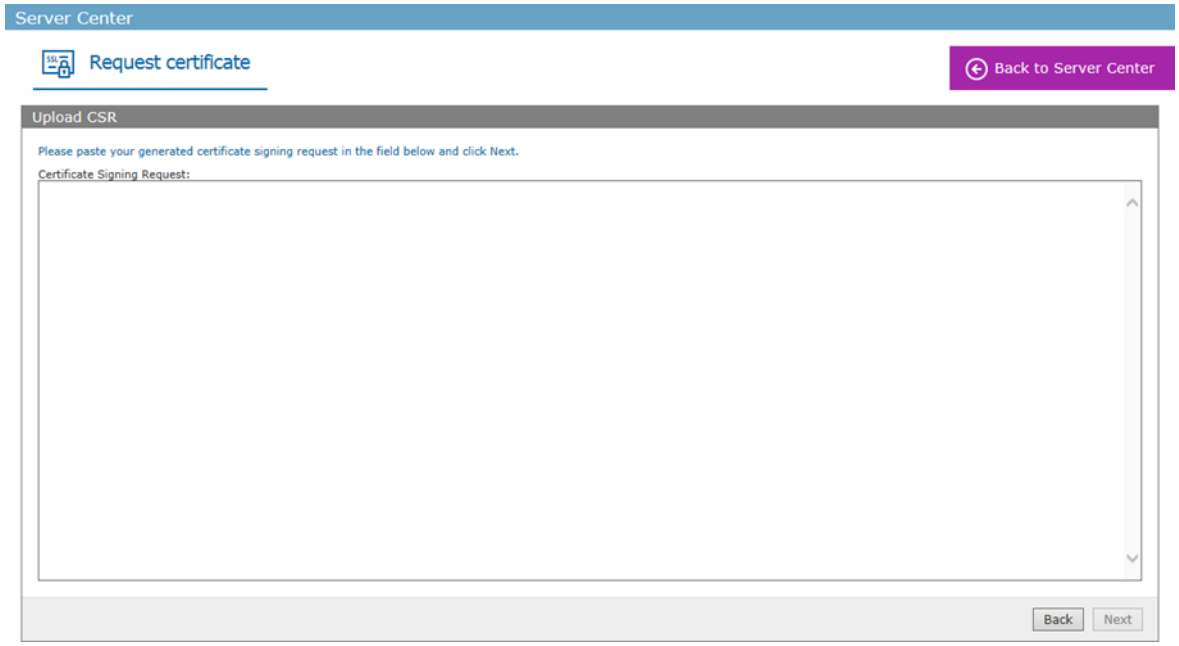

Figure 12 - Visualization of the Upload CSR page

On the next page, check the content of the certificate and change the value if required:

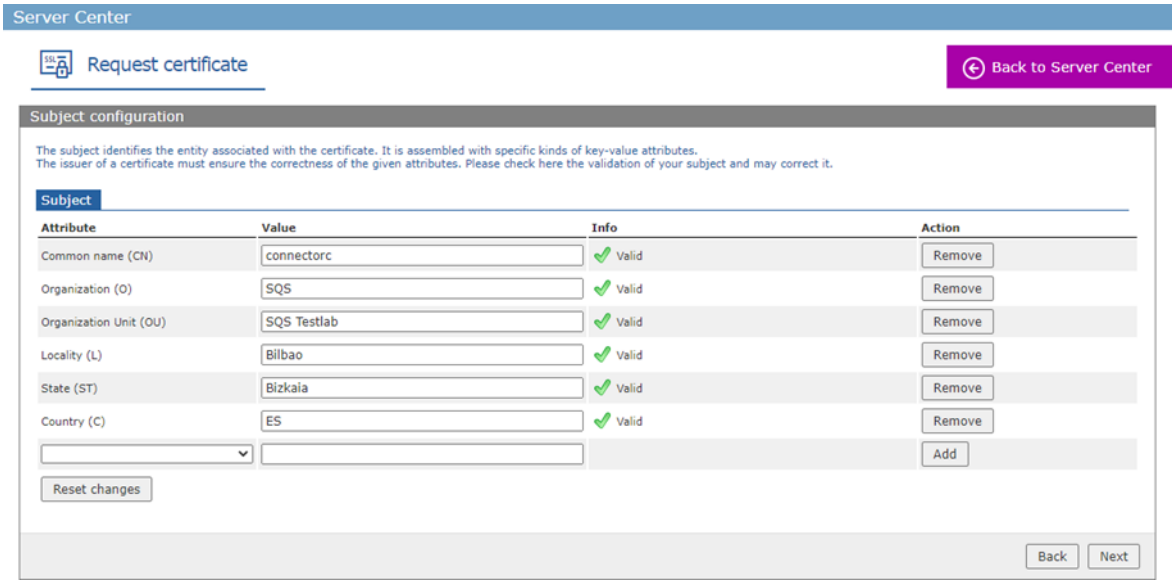

Figure 13 - Visualization of the subject configuration

On the next page you have the possibility to add multiple domains.

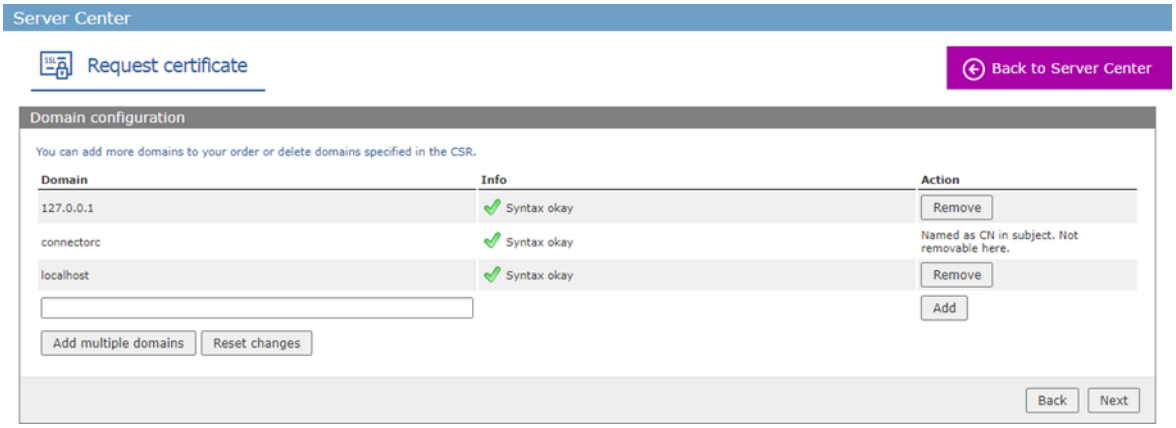

Figure 14 - Visualization of the domain configuration

Fill the text field with the new domain and click on new.

It is also possible to remove Domains from the CSR. The main domain, which is present in the CN of the CSR, cannot be removed.

On the next page, it is possible to add e-mail addresses, which should receive all certificate-relevant information (e.g., expiration and revocation e-mails).

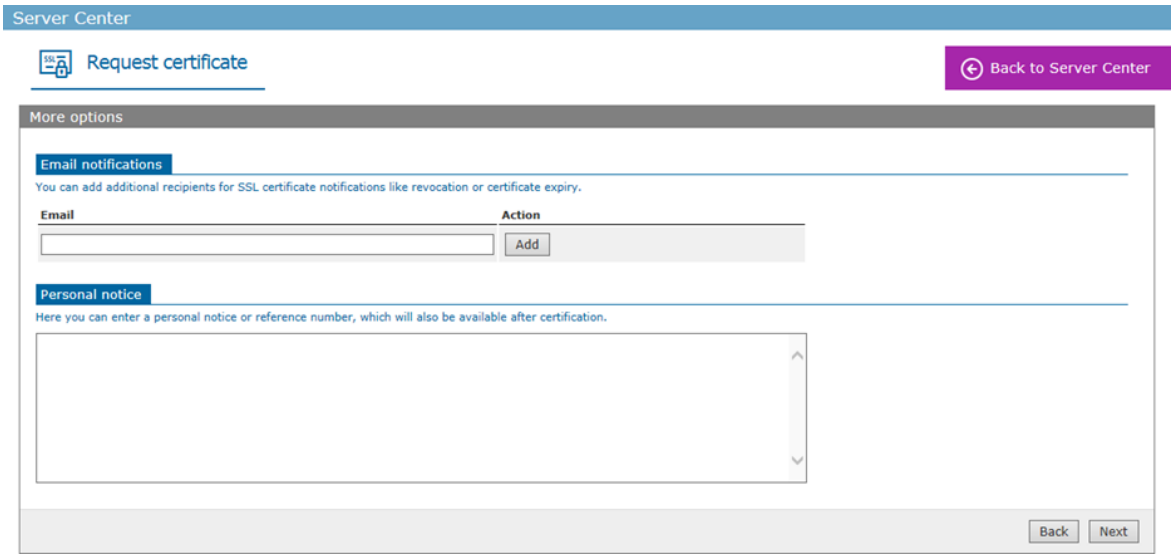

Figure 15 - Visualization of the "more options" page

It is also possible to write a personal notice, which can later be viewed. This can be used to store some information, which should be visible to the rest of the team.

The last page will show a summary of the certificate order. Please make sure that everything is correct; once the order has been placed, it is impossible to change it anymore.

Once you have verified that everything is correct, click on Order.

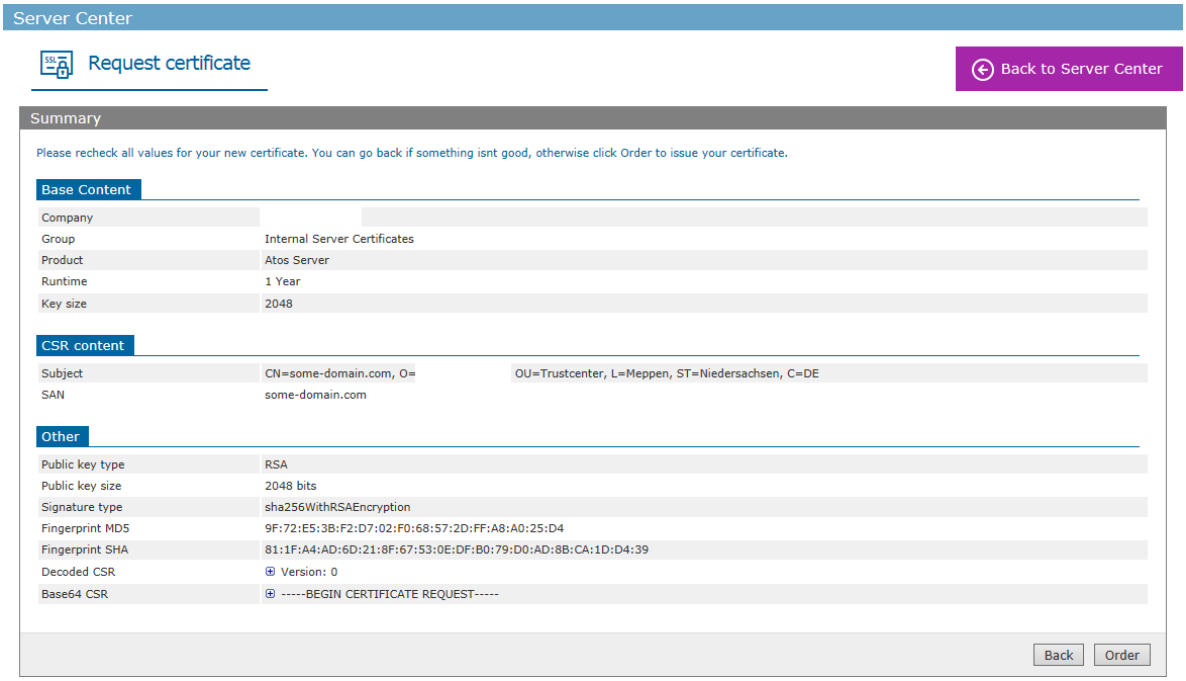

Figure 16 - Visualization of the summary of the certification request

The certificate-issuing process will start immediately and will take a few minutes.

Once you have the certificate, you can easily use it in your component.

STEP 3: Register Data Consumers and Providers and Configure Data Offer from the Data Providers

This procedure is automated by Postman collection. The postman collection is based on the DSC swagger API. These API calls are necessary to Register the Data Consumers and Data Providers to the MDB and generate the Catalogs, Offers, Representations and Artifacts (which is the data itself) inside the Data Space.

The complete API documentation can be accessed using “your IDS component IP”/api/swagger-ui/index.html

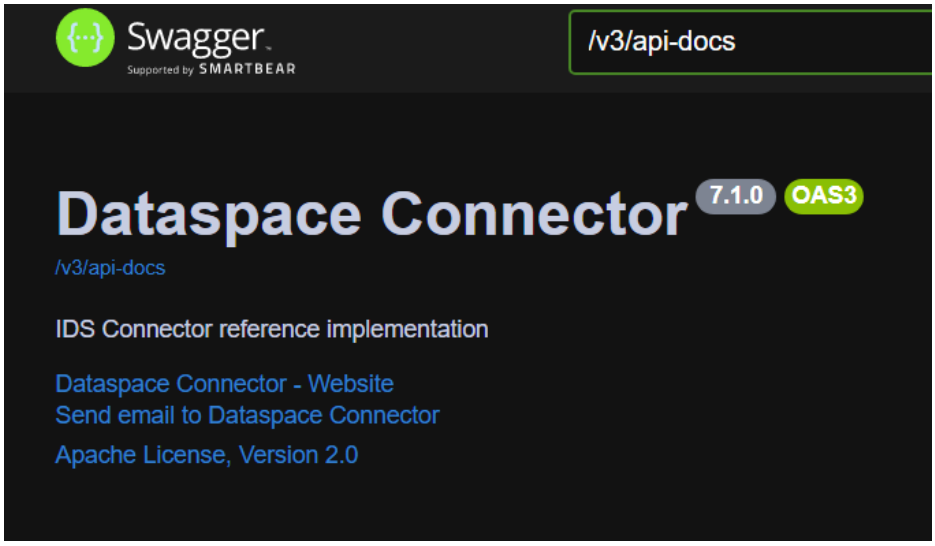

Figure 17 - Dataspace Connector

For more in detail information about the API, check IDS documentation () here.

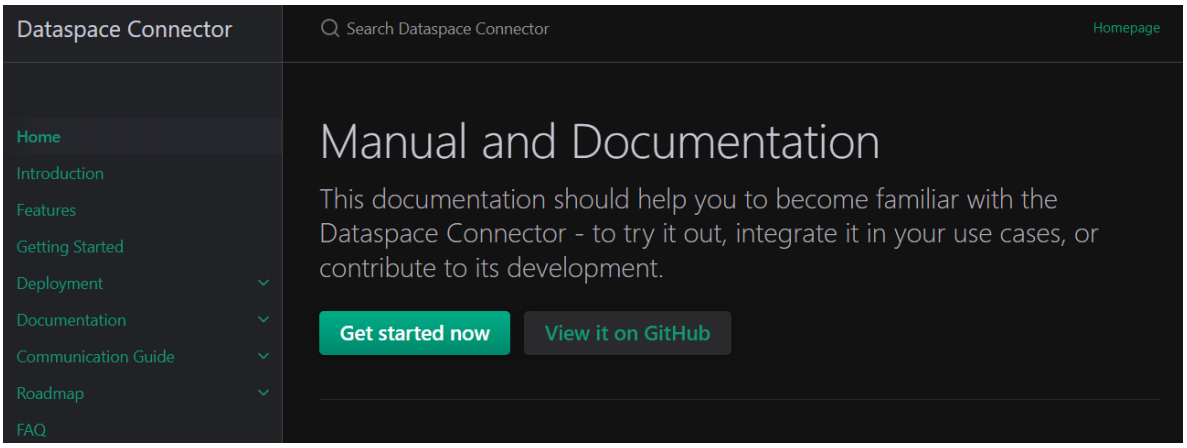

Figure 18 - Manual and Documentation from API check (IDS)

2.2.1.2.2 REGISTRATION PROCESS STEPS

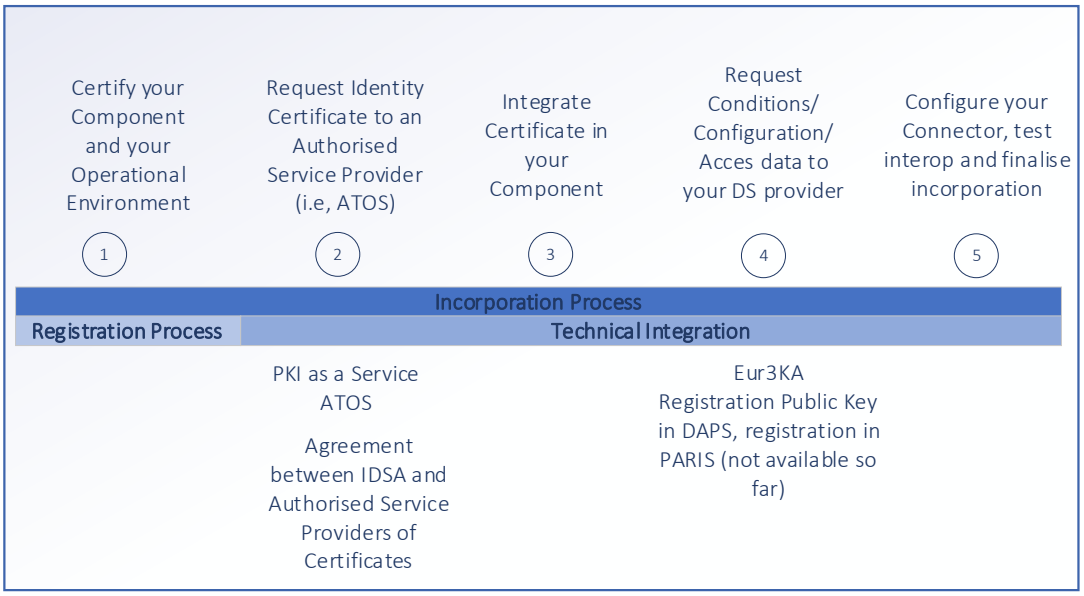

Figure 19 - Incorporation Process (2)

STEP 1: CERTIFICATE YOUR COMPONENT AND YOUR OPERATIONAL ENVIRONMENT

Requester: Participant (in our case, Data Suppliers and Data Consumers) Responsible: IDSA

The evaluation of “Components” and “Operation Environments” is performed by “Authorized Evaluation Facilities”. The Certification is issued by IDSA.

First, an Evaluation Facility is appointed to perform the independent evaluation of the Component (Connector) and the operational environment of the participant-entity sharing data. The corresponding evaluation reports are produced.

After this evaluation has been carried out, the reports are handed out to the certification body (IDSA). If approved, the service provider is aware of the component's validity and operational environment.

- Participants receive a Participant Certificate indicating its operational environment is managed in a secure manner
- The Core component receives a Core Component Certificate, indicating the component meets the required technical specifications.

With both certificates issued by IDSA, the Participant Certificate, and the Core Component Certificate, the Participant can request a digital X.509 certificate for identification, authentication, and encryption.

Then, the user/client requests the identity certificate to a Service Provider.

STEP 2: REQUEST AN IDENTITY CERTIFICATE FROM YOUR SERVICE PROVIDER (I.E. ATOS).

Requester: Participant Responsible: Authorized Certificate Authority

The Certificate Authority (CA) should offer an online platform to automate the certificate-requesting process. The platform should include the following functionality:

- The platform should provide the option to choose from an agreed variety of technical requirements for the X.509 certificates.
- Certificate properties:
    - Key algorithm and length
    - Hash Algorithm and length
    - Validity Period
    - CN (Common name), OU (Organizational Unit Name), O (Organization Name), C (Country Name); subject Altname (X509v3 Subject Alternative Name): is filled with DNS entries / IP addresses of the Connector

X509 Certificate Characteristics used in SQS IDS infrastructure

CERTIFICARE ITSELF	CURRENTLY USED	PLAN FOR THE FUTURE
key algorithm	RSA (2048 bits)	secp256r1
hash algorithm	SHA256ecdsa	SHA256ecdsa
validity	3y	3y

SUBCA SIGNER	CURRENTLY USED	PLAN FOR THE FUTURE

key algorithm	secp384r1	secp384r1
hash algorithm	SHA384ecdsa	SHA384ecdsa
validity	5y	5y

STEP 3: INTEGRATE CERTIFICATE IN YOUR COMPONENT.

Responsible: Participant (Provider & Consumer)

When the Certificate Authority approves the Identity Certificate request, the user/client will be provided with a certificate. This will include the public key corresponding to the private key used in the certificate signing request, which will have to be configured in the component.

The private key will be used for making a Dynamic Attribute Token request, and the public key will be used by the Dynamic Attribute Provisioning Service (DAPS) to ensure that the user/client is who they say they are.

STEP 4: REQUEST CONFIGURATION/ACCES DATA TO YOUR DS PROVIDER.

Requester: Participant
Responsible: Data Space Provider

Once the user/client has installed the provided certificate, they can request access to different Data Spaces they would like to be part of. The incorporation process will be up to the Data Space provider and their own environment requirements.

These may include following specific industry standards and/or hardening security on data usage.

If access is granted, the Data Space Provider uploads the public key to the DAPS.

STEP 5: CONFIGURE YOUR COMPONENT, TEST INTEROPERABILITY, AND FINALISE INCORPORATION

Requester: Participant
Responsible: Data Space Provider

Once the user/client has been accepted to the Data Space, the component's adaptability phase will begin. The component will be configured to establish a communication channel with the other components where interoperability, functionality, and security testing will take place.

2.2.1.3 COMPONENTS OF THE SERVICE LAYER

2.2.1.3.1 Application to Data Providers and Consumers

The application is used to see all the traffic inside de Data Space. This is how it looks once opened.

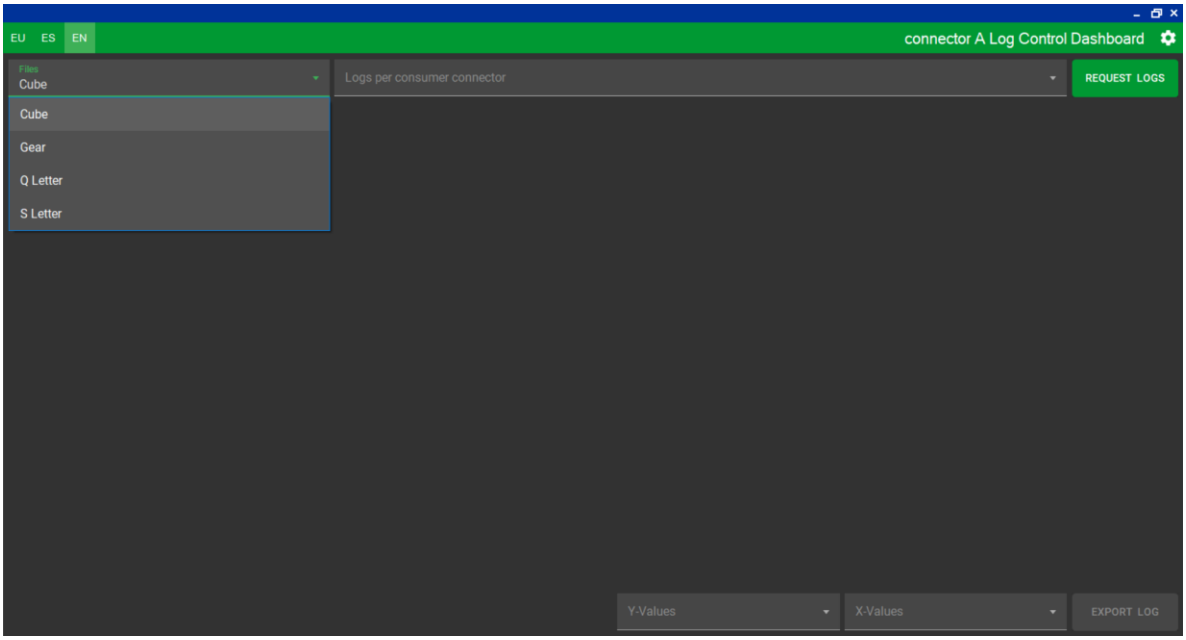

Figure 20 - Visualization of the Application to Data Providers and Consumers

When the “Request Logs” button is pressed, all the files inside de Data Space are loaded into the file combo box.

Then the user can select the file to see the agreements based on this file.

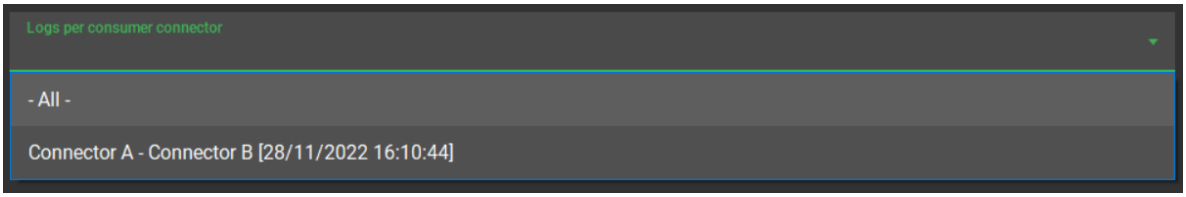

Figure 21 - Visualization of the Provide-Consumer agreement

Here appears the Provider-Consumer (Connector A – Connector B in this case) agreement and the date when the agreement was made.

Now the user can select the data to visualize (downloads or transactions) and the time interval to be grouped.

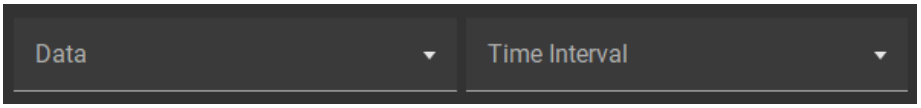

Figure 22 - Visualization of the time and data options

Once selected, the user can see graphics based on the downloads and transactions made to that file.

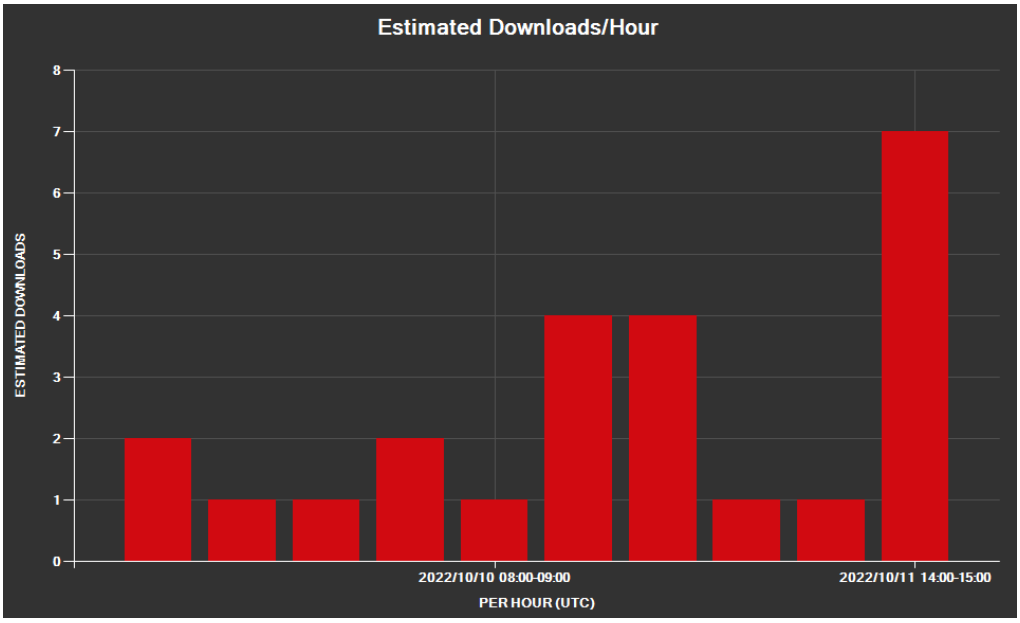

Figure 23 - Example of a possible visualization regarding downloads

If the user clicks the “Export log” button (down right), a CSV file will be generated and saved in the selected directory. The CSV file will have all the information related to the transactions made for the selected file (including time stamps, token ids, etc).

2.3 Validation and Verification Service Platform

Q-Med Tech is a web platform based on Mango Apps, created by SQS. It is designed to support the provision of certification services as well as the marketing of certified products and services within the medical device community.

Users

This platform is designed for three types of users, whose role is described in more detail in deliverable D3.2:

- **Certification Team**: offer customised certification services.
- **Technology Providers**: providers of solutions and production capacity, who register their products and processes according to the established certification criterion.
- **Consumers**: have access to the Marketplace of certified products and processes and can negotiate with the providers.

Registration is mandatory for both certification providers and Technology Provider. For customers, certification is not mandatory, but some functions are not available until registration has been formally completed.

Market Place & Certification and Registration Site

The platform has two major components:

- **Market Place**, where Consumer users can register to purchase already certified and validated products and/or processes. Also, Consumers can check several technical repositories:
    - Catalogue of Providers, contains a list of all the technology providers (from now on Tech Providers) conforming Q-MedTech, already registered in the platform.
    - Catalogue of Certified Solutions, accessing here, consumers can find every technical solution (processes and products) in the platform. Tech Providers previously registered these solutions.

Technical Information about Certifications, where consumers find a repository with all the information required (documentation, forms, etc) in the roadmap plan to certify a product, technology, or medical device.

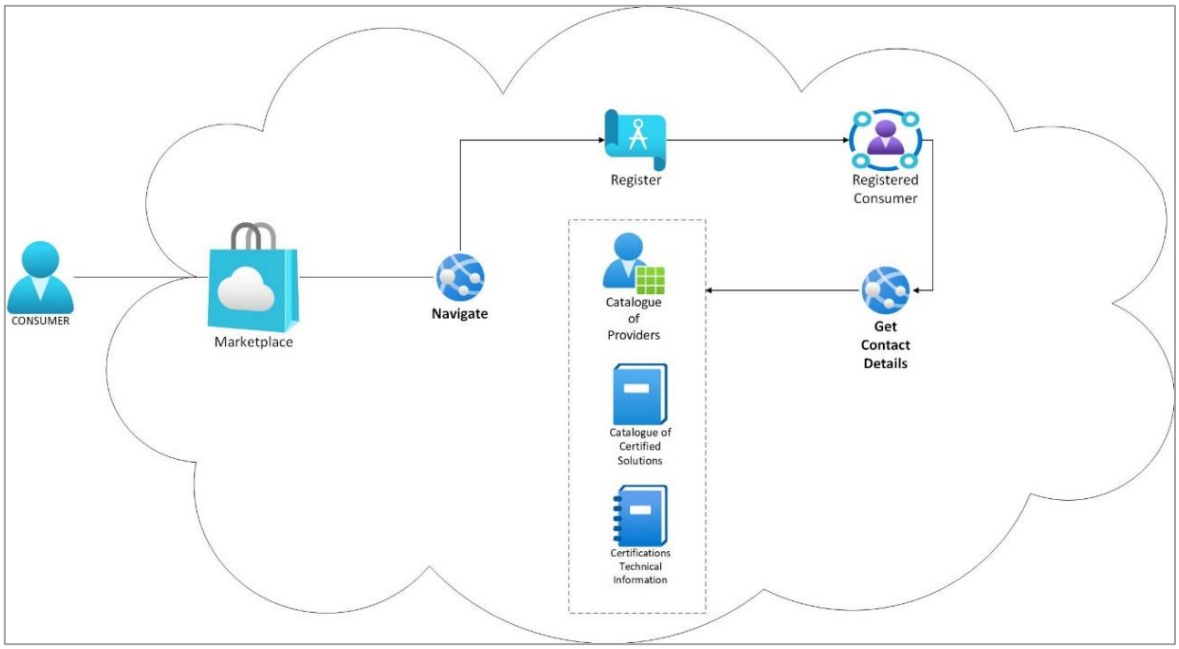

Figure 24 - Q-Med Tech platform Marketplace

Certification Site, where Technology Providers can request the Certification or Registration of a medical device, technology and/or capability, and where Certification providers can design and develop the corresponding certification plans.

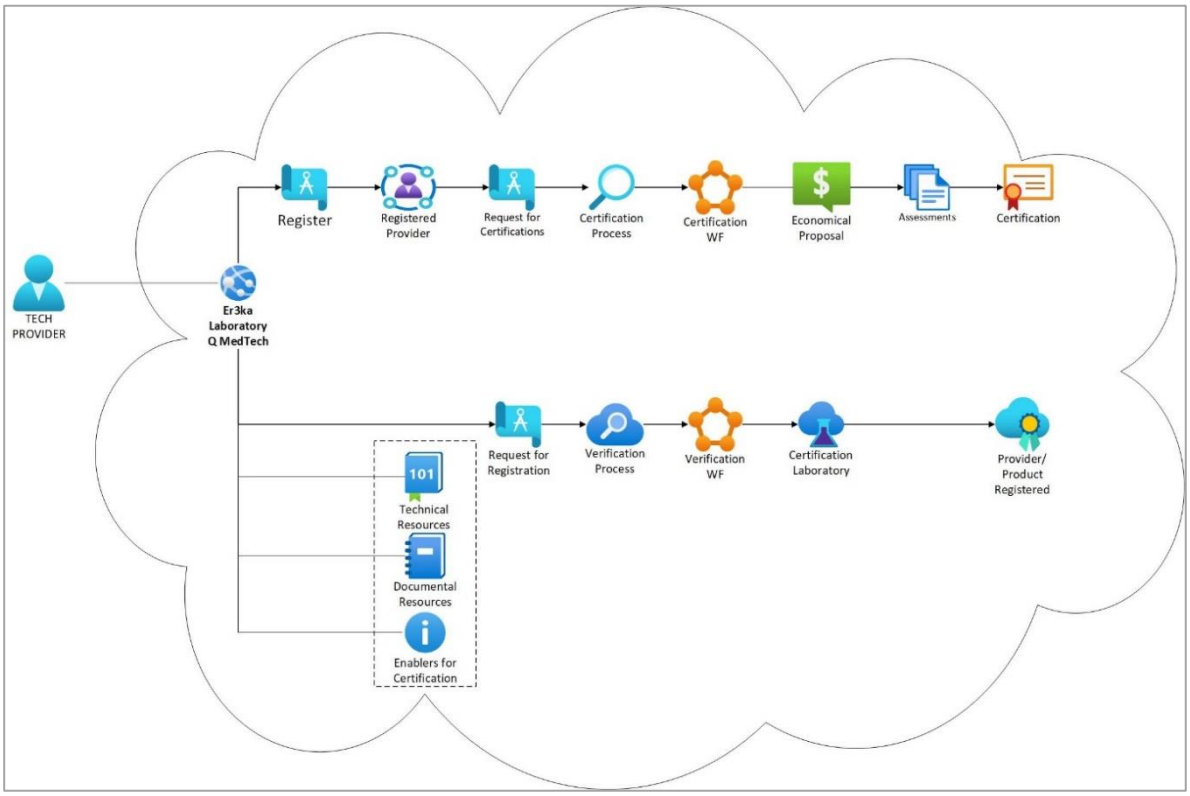

Figure 25 - Q-Med Tech platform Certification Site

2.3.1 Front Office of Q-Med Tech platform

The **Front End** gives access to the (i) **Certification Process**, (ii) **Registration Services** and (iii) **Market Place**. This Front End provides a common workplace for both parties, Technology Provides and Certification Team, where they exchange all the documents and notifications related to the certification process.

2.3.1.1 Certification Process

During this certification process, two actors are involved:

- **Technology Providers** (providing products and/or processes) and
- **Certification Team** (technical team engaged in the review and validation activities of the product and/or processes delivery).

The next picture describes the complete workflow of the certification process (the numbers above pictures are the reference of the chapter in the following pages that describe the process):

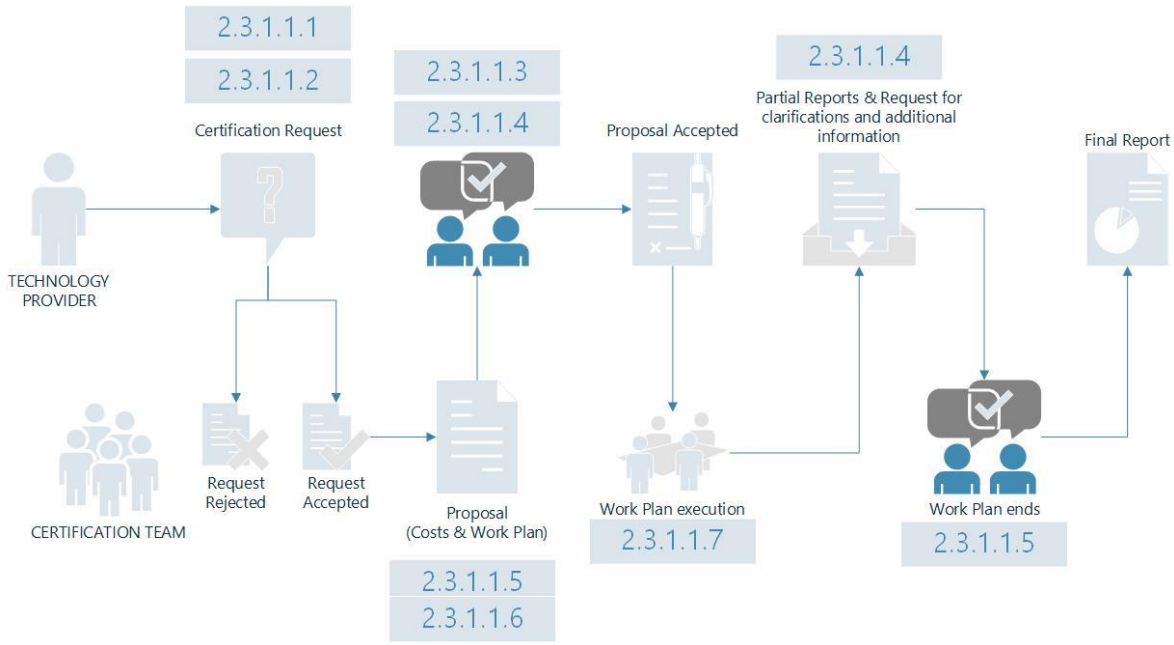

Figure 26 - Certification process workflow

Please find described below both workflows, Technology Provides and Certification Team, with every step that must be done for them during the certification process.

TECHNOLOGY PROVIDER

2.3.1.1.1 Access to catalogue of Enablers for certifications

Inside this section, Technology Providers can find several resources, called Enablers, that help them to prepare the certification process in case is needed (this step is not mandatory).

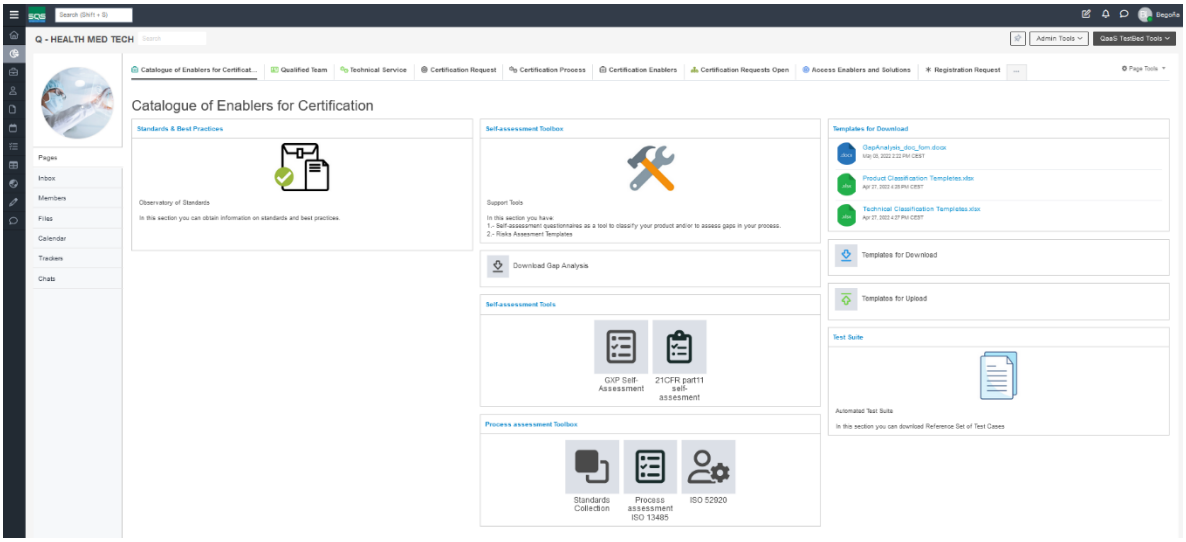

Figure 27 - Q-med Tech platform enablers

Currently, Q-Med Tech platform offers the following Enablers:

- **Standards & Best practices**, where Technology Providers can find information about the regulations involved in the certification process (ISO 13485, ISO 52920, GXP, and 21 CFR part 11).
- **Self-assessment Toolbox**, where Technology Providers can find assessment tools:
  - Access to several **questionnaires assessments** about the regulations listed in the previous section (and perform a self-assessment work) for both products and processes,
  - Download a **GAP analysis** for both product and processes,
  - Download **Templates** and fulfil the documents to provide evidence for the future Certification Team in charge of the certification process.
  - Use the automated **Test Suite** and download the proper reference set of test cases related to product or process regulations.

2.3.1.1.2 Request for certification

After the Technology Providers gather all the information (if it had been necessary) helped by the Enablers (assessment questionnaires completed, GAP analysis templates fulfilled, etc.), they can create a request to start the certification process:

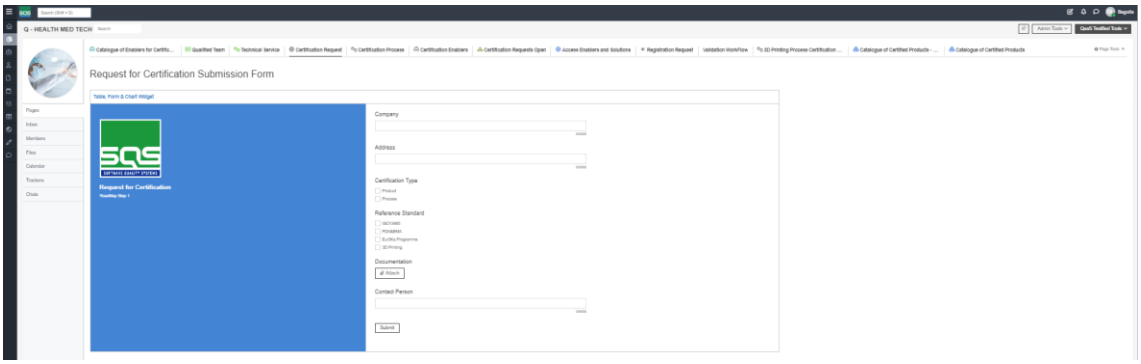

Figure 28 - Request to start the certification process

In this form, Technology Provider must provide:

- Company: company name.
- Address: company address.
- Certification Type: select what is going to be certified, product, or process.
- Reference Standard: select the corresponding regulation for the product or process.
- Documentation: files to be attached in the request that the Certification Team will require during the certification process.
- Contact Person: email from the contact person in the Technology Provider. This person is in charge of the communication between the Technology Provider and the Certification Team.

Once all the information is provided, Technology Provider must click on submit to send it to the Certification Team, which will review everything and will notify if it's accepted or not.

If it is not accepted, Certification Team will notify what must be done before starting the certification process, and Technology Provider must update the requested information with it.

If accepted, the Certification Team will notify that the registration is complete.

2.3.1.1.3 Contacting the certification support team

In this section, Technology Providers can access information about the Certification Team in charge of the certification process:

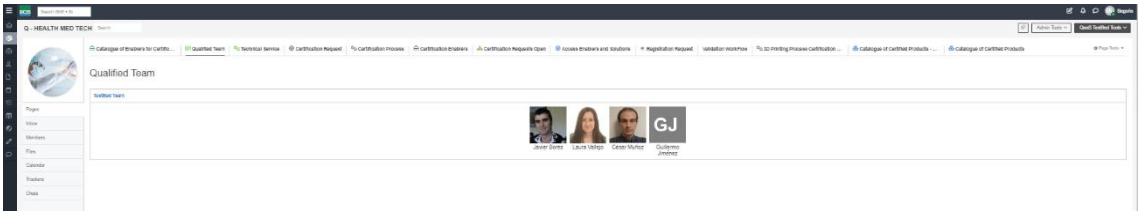

Figure 29 - Certification Team information

They can find contact information about the team and write them during the certification process – before and after – to ask about the details of the information that must be given to certify the processes or products.

2.3.1.1.4 Checking the status of the Certification Process

Inside this section, Technology Provider visualizes the current status of the certification request:

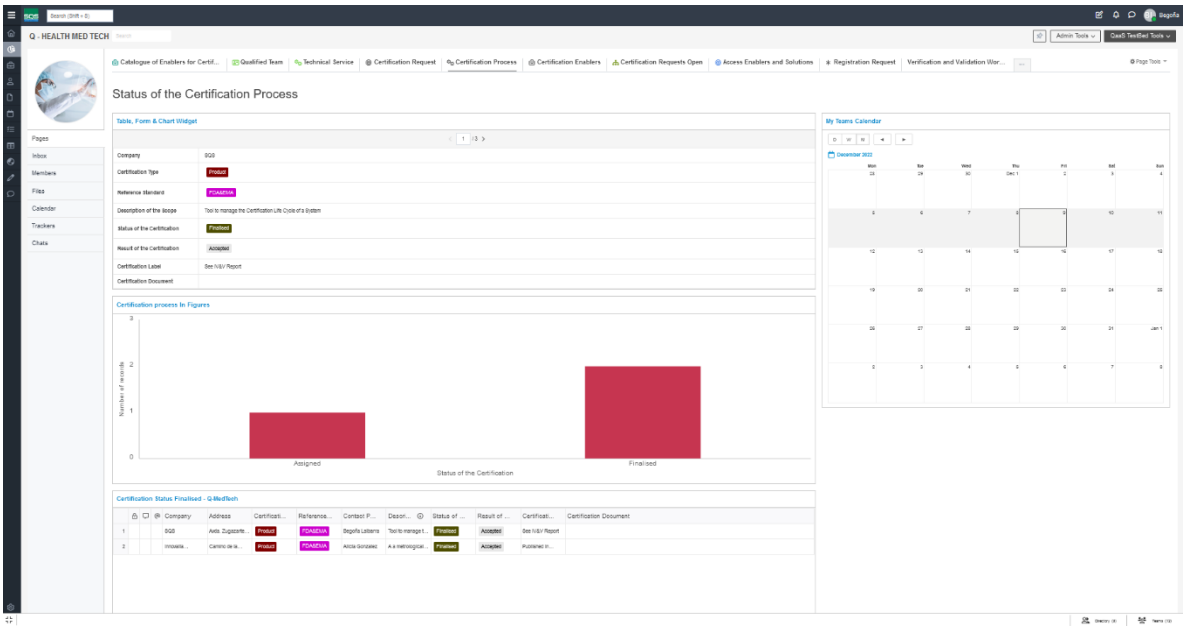

Figure 30 - Visualization of the status of the certification process

There, the following information is showed:

- Company: Technology Provider's company name.
- Certification type: product or process.
- Reference standard: name of the regulation(s) of the process.
- Description of the scope: a short summary of the certification process.
- Status of the certification: status of the certification request.
- Result of the certification: the result of the certification process.
- Certification label

- Certification document

Technology Provider can see at a glance the status of the requests made, the next work plan events, and the actual status of all the works done by the Certification Support Team assigned. In that way. Technology Provider can check that SLA (Service Level Agreement) is guaranteed.

Here, Technology Provider will upload the documents and clarify the information needed for the certification process when Certification Team asks for it.

At the end of the certification process, the final report will be uploaded here.

CERTIFICATION TEAM

2.3.1.1.5 Reviewing certification requests

Once the Technology Provider creates a request, Certification Team must review all the information gathered:

a. If the request is out of scope, the request is rejected, and Certification Team notify to the Technology Provider, if not,
b. in case something is missed, Certification Team notifies to Technology Provider, and asks for clarifications.

When all the information asked is reviewed, the Certification Team assigns a team of a technical person from the Certification Team to this certification process and creates a project inside the certification site, where both parties, Technology Provider and Certification Team, exchange information during the certification process.

Inside this dashboard, the Certification Team can access the documentation attached to the request made by the Technology Providers and update the status of the work related to the validation of products and processes.

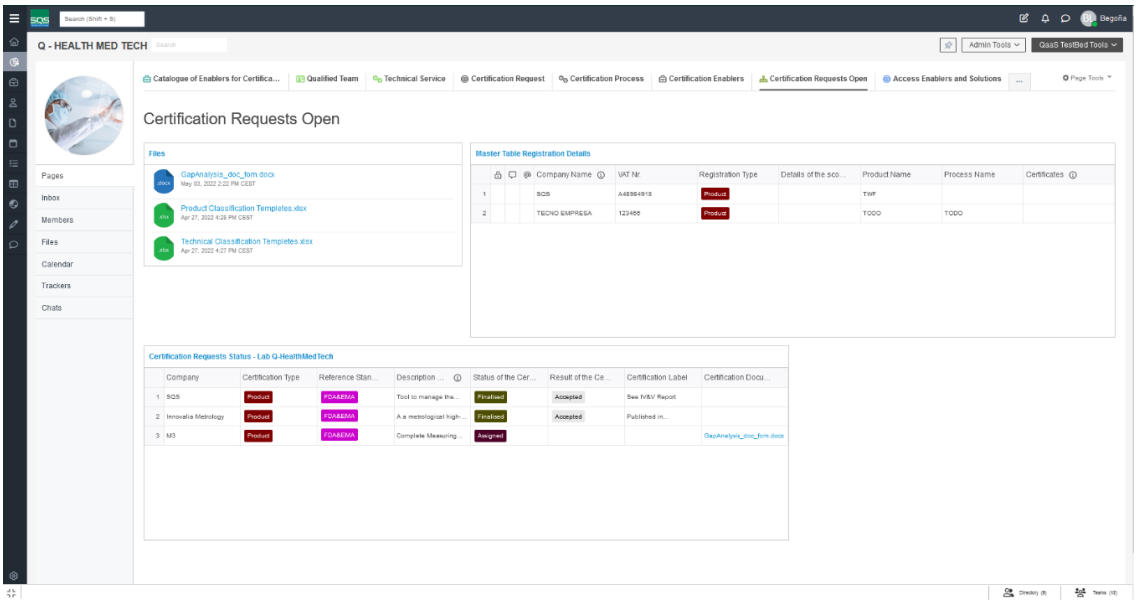

Figure 31. Visualization of the Opened Certifications Requests

2.3.1.1.6 Creating a verification and validation plan

Since the request is finally accepted, Certification Team starts creating the Certification Plan and the Economic Proposal.

The Certification Team creates a document with the detailed economic and technical proposal and the work plan and sends it to the Technology Provider. This document must be accepted to begin with the work plan detailed in it.

Once the proposal is accepted, the Certification Team is notified and starts the work.

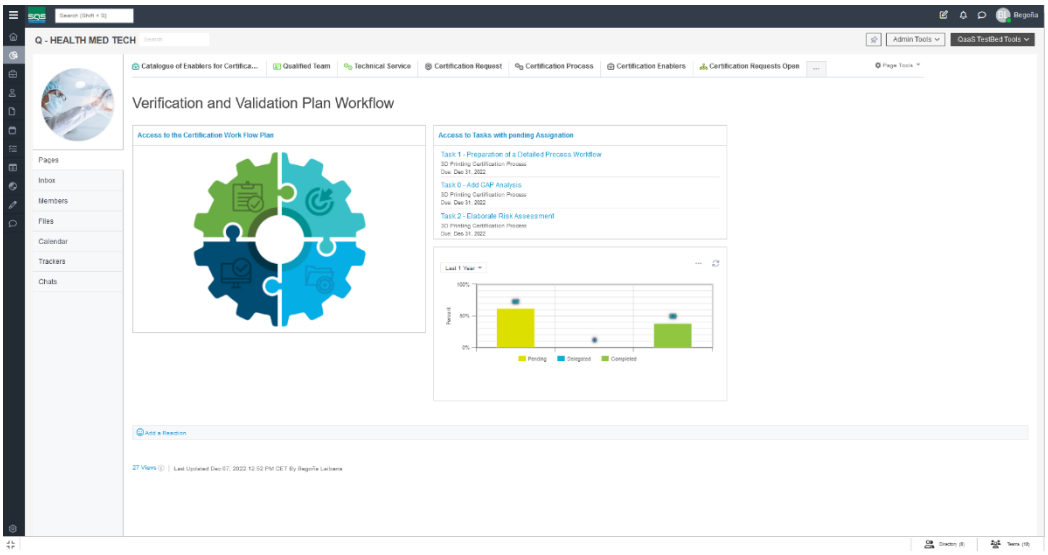

Figure 32 - Visualization of the Plan Workflow

2.3.1.1.7 Executing work plan

After the proposal is accepted by the Technology Provider, Certification Team can find here all the templates and software involved in the certification process.

The team downloads all the previously accepted software and templates. Every document and software provided for this phase of the certification process is previously validated.

Internally, when errors appear, will be reported using Jira, and several reports will be uploaded into the Q-Med Tech platform to inform Technology Provider of the certification process status.

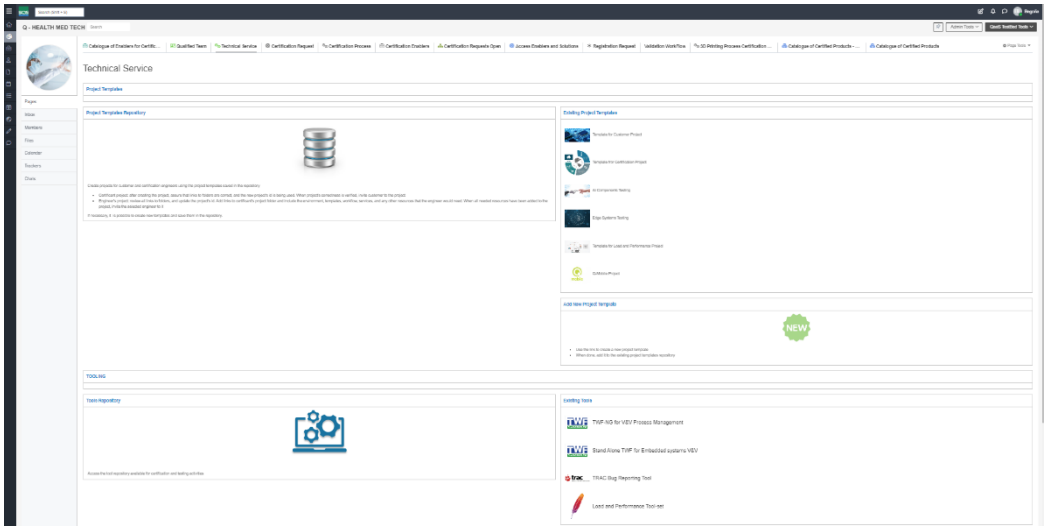

Figure 33 - Visualization of the Technical service

During the process, Certification Team will send partial reports to the Technology Provider, and internally register all the errors found in Jira. Technology Provider must review all these partial reports, sending according to a SLA previously agreed.

Technology Provider must send all the additional documents, information and clarification asked by the Certification Team to complete the work plan.

After the plan is finished, Certification Team will send a final report to the Technology Provider.

2.3.1.2 Registration process

2.3.1.2.1 Request for Registration Submission Form

After the Validation and Verification process, the product is certified and ready to be uploaded into the Market Place. Technology Providers must submit the following form:

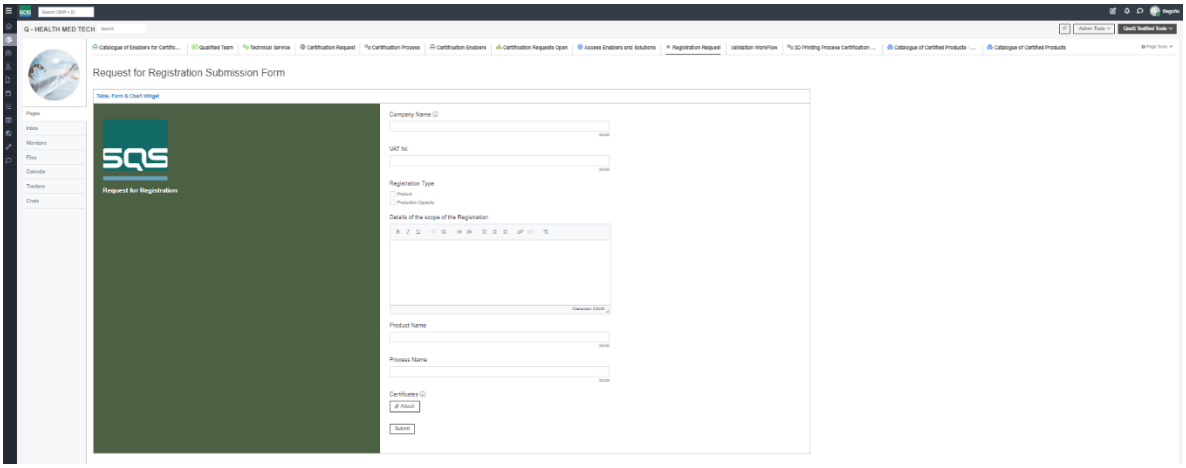

Figure 34 - Visualization of a Request for Registration

Technology Providers must provide:

- Company Name: Technology Provider company's name.
- VAT Nr.: Value Added Tax that corresponds to the Technology Provider location.

- Registration Type: product or production capacity (process).
- Details of the scope of the Registration: summary of the product or process of the request.
- Product Name: product's name.
- Process Name: process' name.
- Certificates: The technology Provider attaches the certification provided by the Certification Team or third parties.

Every registration request is reviewed and accepted by the Certification Team, and after that, it is uploaded into Market Place, where Consumers can buy it.

2.3.1.3 Market Place

The **Marketplace** comprises a **catalogue of certified products** and processes ready to be integrated into a medical device manufacturing supply chain. Full details of the product/process characteristics, pricing model, and certification scope are included. Search utilities facilitate a fast and effective navigation process.

Negotiation utilities are not covered by the platform. Access to the corresponding Technology Provider contact details is given to the Consumer after registration, and then, both parties should negotiate the business relationship.

Certification services are provided to both product and process providers (called from now on Technology Providers):

- Process providers.
    - Providers of P**roduction Capacity**.
- Product providers.
    - Providers of T**echnology**.
    - Providers of intermediate/final M**edical Devices**.

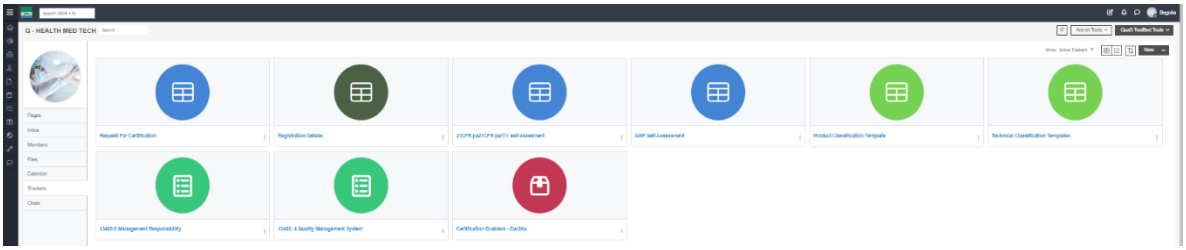

Figure 35 - Front end of Q-Med Tech platform

In Q-Med Tech platform, we can find two different workflows for each type of user:

- **Technology Providers** where they can request the certification for their products or processes,
- **Certification Team**, where certification team can upload the work done during the certification process.

2.3.1.3.1 Access Product Provider and Solutions

Before the certification process, **Technology** Providers may use several resources previously the request, such as:

- **Basic products**: technical and Usability enablers, SW or SW/HW Components with a generic purpose.
- **Core products:** Combination of Enablers to provide a service/functionality.
- **Core solutions:** Specific implementation of Core Products and/or Enablers to implement a process.

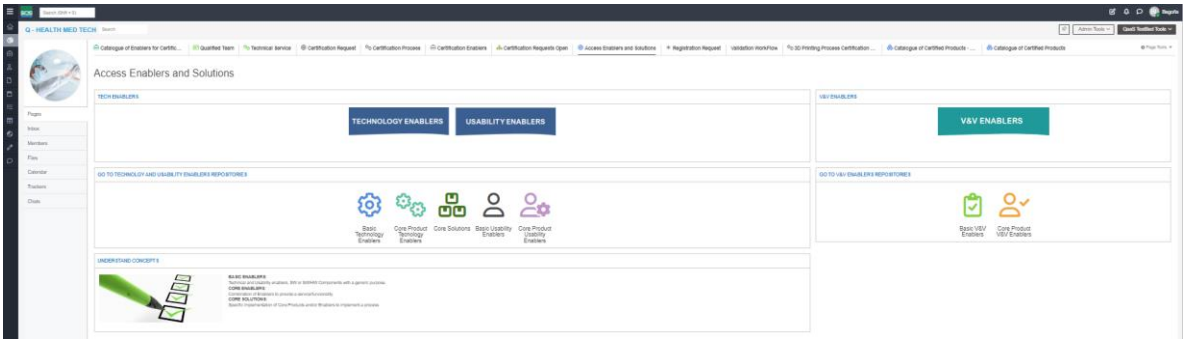

Figure 36 - Visualization of the access to enablers and solutions

Product providers can access documentation that could be used to perform some testing and check the products or processes before the request for validation.

2.3.1.3.2 Catalogue of Certified Products

After being registered, the Certification Team review the information and details attached, and, in case there is no additional information or documentation requested, the product is uploaded into the Market Place:

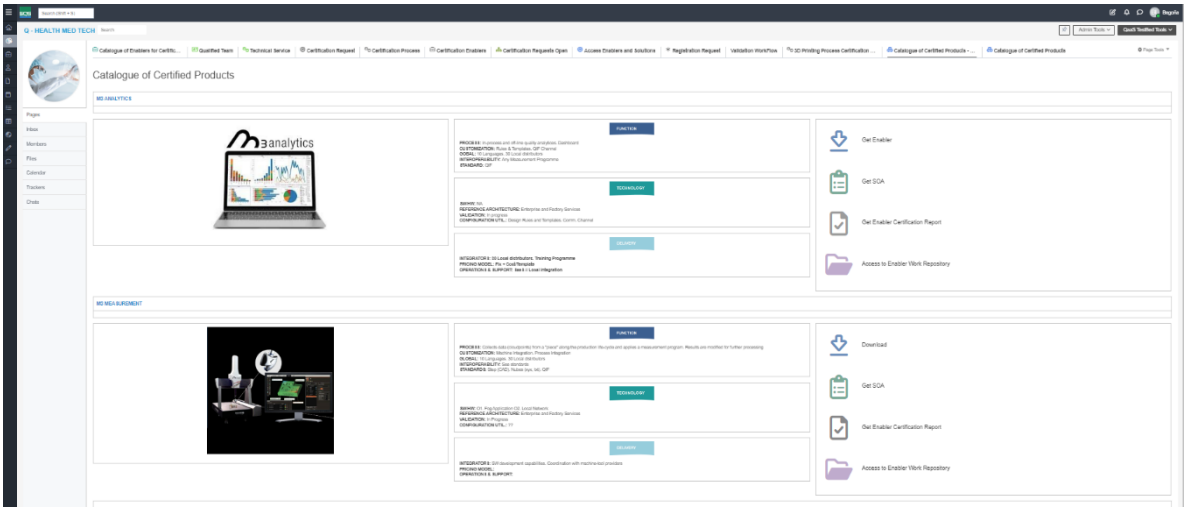

Figure 37 - Visualization of the catalogue of certified products

Here, other Users can access the complete catalogue of certified products. For each one, there is a complete description, regarding the function, technology, and delivery of the product/process, and let us access to:

- Product Provider: access to the product/process enabler.
- SOA: service-oriented architecture, listing all components and description about the product/process certified.

- Product Provider Certification Report: Users can download the complete certification report.
- Product Provider Work Repository

2.3.2 Back Office of Q-Med Tech platform (Certification Site & Access to the laboratory)

This site is only accessible to Registered Certification Providers. This site offers a complete set of tools to design and execute a Certification Roadmap adapted to the characteristics of the system to be certified.

It also offers communication and data-sharing tools between Certification Providers and Customers, following tools are detailed:

Technical Resources

The platform includes several software resources to make a pre-testing for the products and/or services for the certification and validation process.

Using these resources, providers can perform a previous verification process, to execute a similar validation and certification roadmaps, making it easy and faster the workflow for the Team in charge of it.

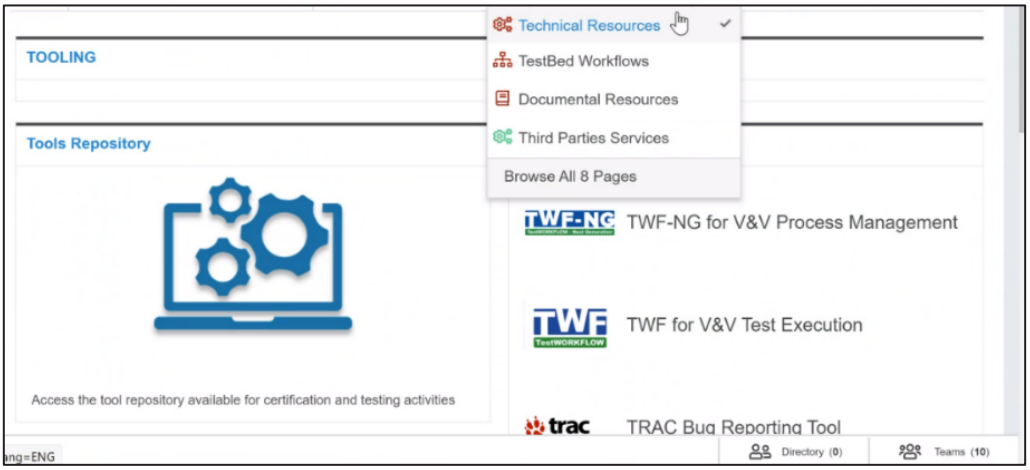

Figure 38 - Technical Resources of the platform

Documental Resources

In this repository, providers will find all the documents related to the certifications for the products and services.
With them, they can pre-check all the requirements needed to ensure that the certification and/or validation workflow will be executed successfully.

Also, they can access all the resources related to the several certifications (ISO, FDA, etc) providers supported by the platform.

Enablers for certification

In addition to services, Tech Providers and Certification Providers are given access to a complete set of resources identified as “certification enablers”. These assets are offered to help understand the scope of the certification and to fasten its adoption. The following assets are provided:

- Certification Support Tools.
- Technical Documentation.

2.4 Risk Assessment Services

The Risk Assessment Tool aims to help the users evaluate the existing risks, for example, in the case of repurposing and reconfiguring the production lines regarding COVID-19. This tool contains details like plant size, the distance between workers, or the number of bathrooms. If any of these parameters change, it is necessary to evaluate the risk again.

One of the objectives is to identify the risks of the new configuration, taking into account the current guidelines and regulations for COVID-19 mitigation. These guidelines shall then be updated according to future revisions. On top of that, the different countries' rules for COVID-19 were also analysed as well as different areas of operation.

After having the Risk Assessment created and details filled by the responsible, the technician is going to analyse the risk considering the risk mitigation, checking what is the probability of that risk occurring and what could happen if it occurs.

The tool uses AI to give recommendations/suggestions to have better results in the risk assessments, and for example, if a repurposing exists and the distance between workers change, it will suggest the new existing risk. Of course, these suggestions/recommendations will not replace the visit of a professional.

In the end, the tool will deliver a document with all the information that was assessed, which can be printed and fixated in the respective factory.

2.4.1 Risk Assessment workflow

Figure 39 depicts the flow of the tool explaining their interactions, representing all the possible steps that are available in the Risk Assessment tool.

The process starts with the responsible for creating the Risk Assessment template. This template can be based on existing ones or start a new one which will contain different kinds of information like parameter input (like the size of the factory, distance between workers), name, section/category, description, and proposed control measures. While the template is being created the status is “Creating”, but when it is finished, it will pass to “Ready to be answered”. After this, the technician will start to analyse the consequence and the likelihood of each hazard and using the risk matrix will be determined the risk level reaching the status “Answered”.

The risk assessment that was created can be seen in a list, and users can see the following actions:

- consult it and see how historically the hazards were solved.
- see how a place has evolved in terms of risk assessment by seeing the evolution.

- reuse an existing risk assessment and only adapt what is necessary, for example, see if the proposed control measures were applied and if it is needed to add more measures to take it to a safe level.
- If there is a repurposing in the factory, it will trigger to do a new risk assessment
- If any parameter input is changed in an existing risk assessment it will suggest making a new risk assessment in order to analyse the new conditions.

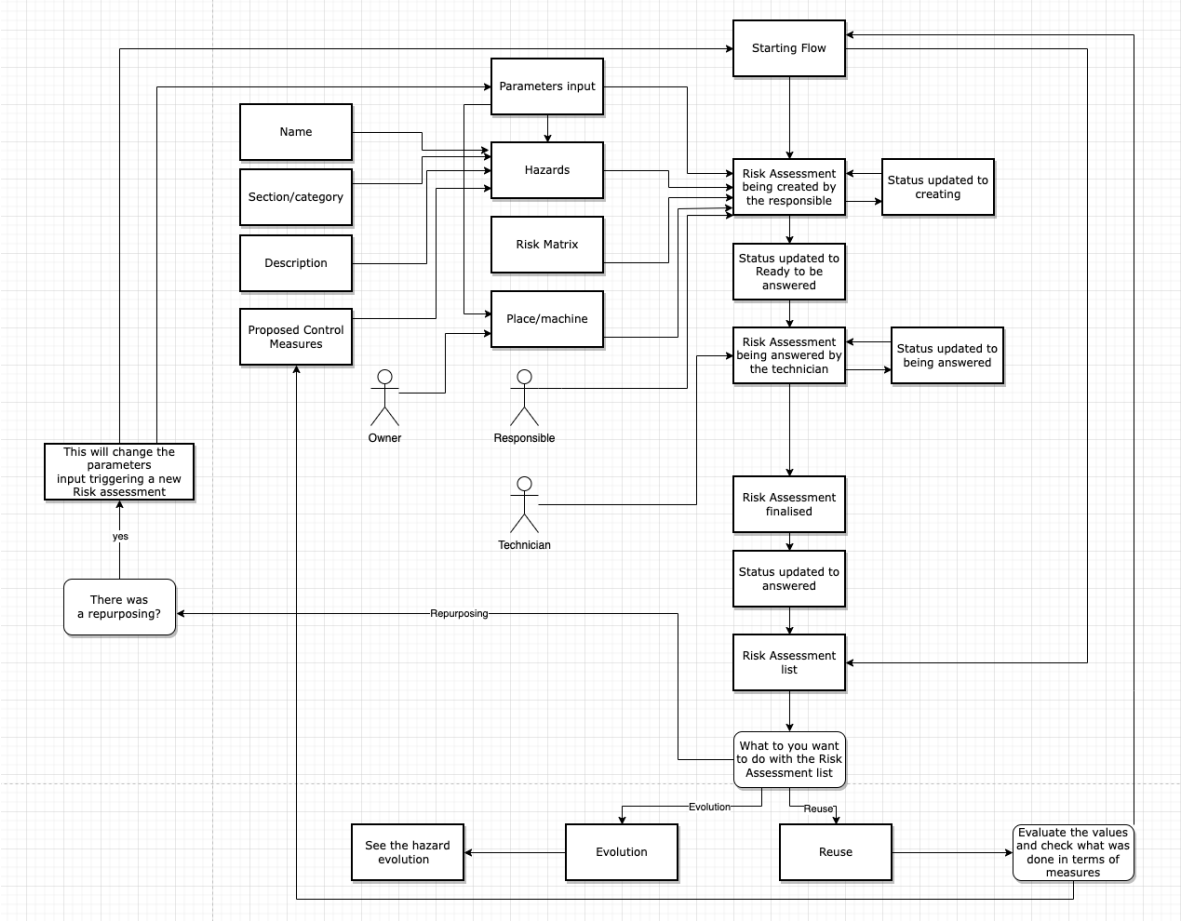

Figure 39 - Tool flow

2.4.2 Functionalities

The available functionalities provided by the Risk Assessment tool are:

- It is protected with login.
- Create Risk Assessment templates with information like name, where it acts, description, and parameters that can interfere with the Risk assessment, like the factory size or distance between workers, risk matrix, and hazard with the proposed control measures.
- Change their status to know when the next person needs to act.
- Use the templates available to create new ones.
- Reuse the old ones and verify if the proposed control measures were applied and helped to solve the problem.
- See evolution through different iterations of risk assessment.

- Trigger a new risk assessment when existing repurposing in the factory or the initially specified parameter has changed.
- During the process, it is possible to edit to be able to add more information or update the existing one.
- There is a risk assessment history that allows users to consult old information to see the type of problems that already existed and how it was solved.
- Provide AI suggestions about how to resolve hazards by looking at the proposed control measures that were used in the past.
- Generate reports with information that can be fixated in the factory to share how the hazard can be solved.

2.4.3 Implementation

The tool was implemented using the Meteor framework being deployed using a docker system. In terms of visual appearance there is a homepage with a navigation bar containing a link to see Risk Assessment templates (the ones that were created by the user) and to create new ones, but there is also a zone where the user sees a set of Risk Assessment and a shortcut to create a new Risk Assessment. The homepage is public, but to access the remaining information is only available with login (Figure 40).

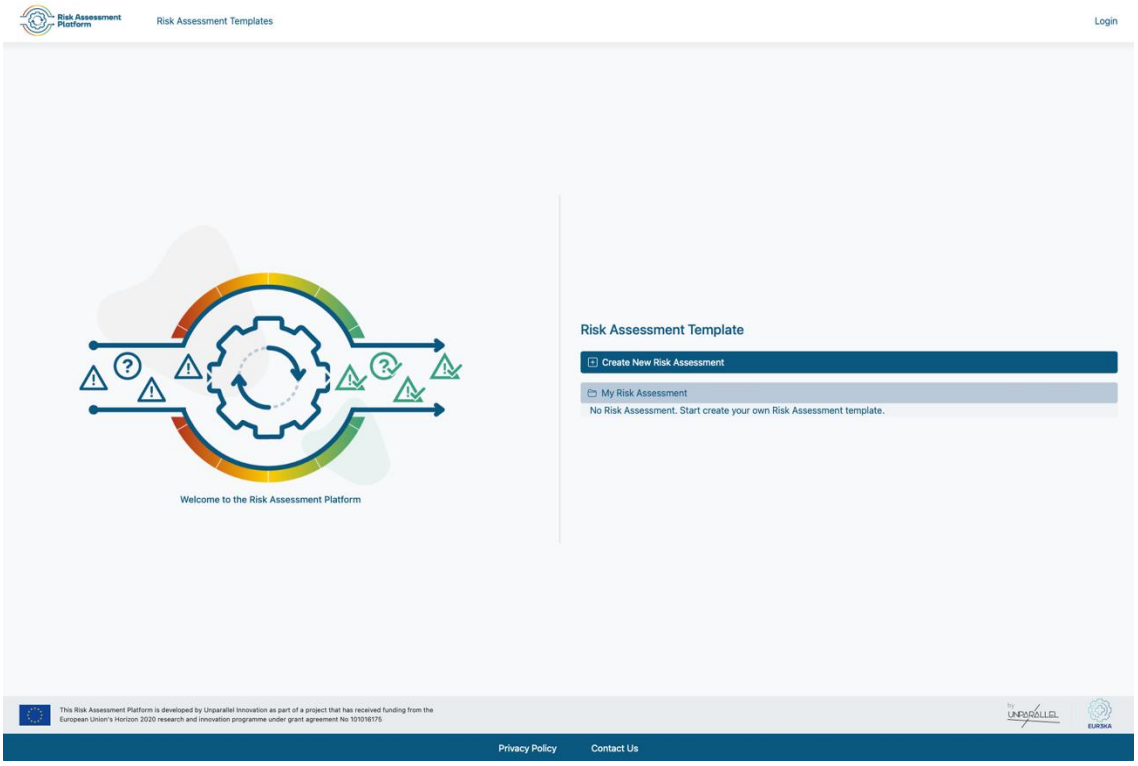

Figure 40 - Risk Assessment homepage

After login into the website user can start creating the Risk Assessment template. It starts by filling up the general information containing information like name, date, status, place and description (Figure 41).

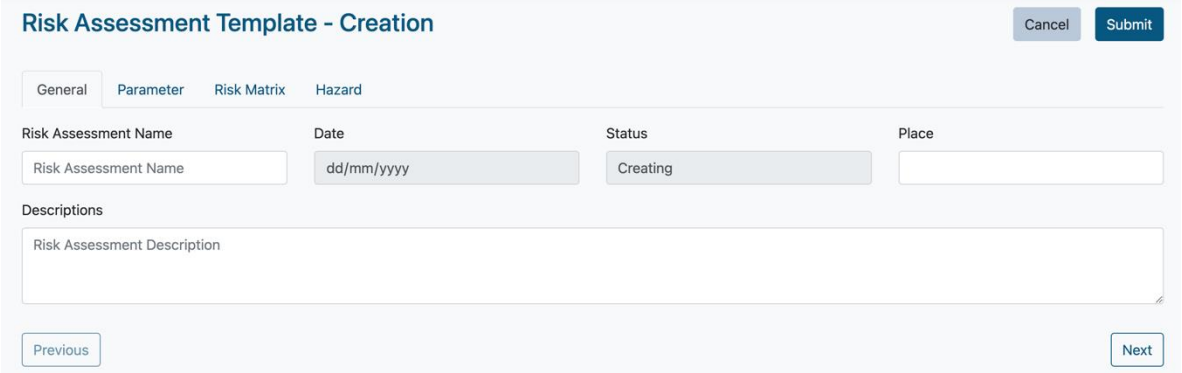

Figure 41 - Risk Assessment Creation General tab

Passing to the next tab (using the “Next” button or “Parameter” tab) it has information about the parameters of the factory (Figure 42), but for now, it is only about creating the parameter and giving a unit and description, later, it will be given a value.

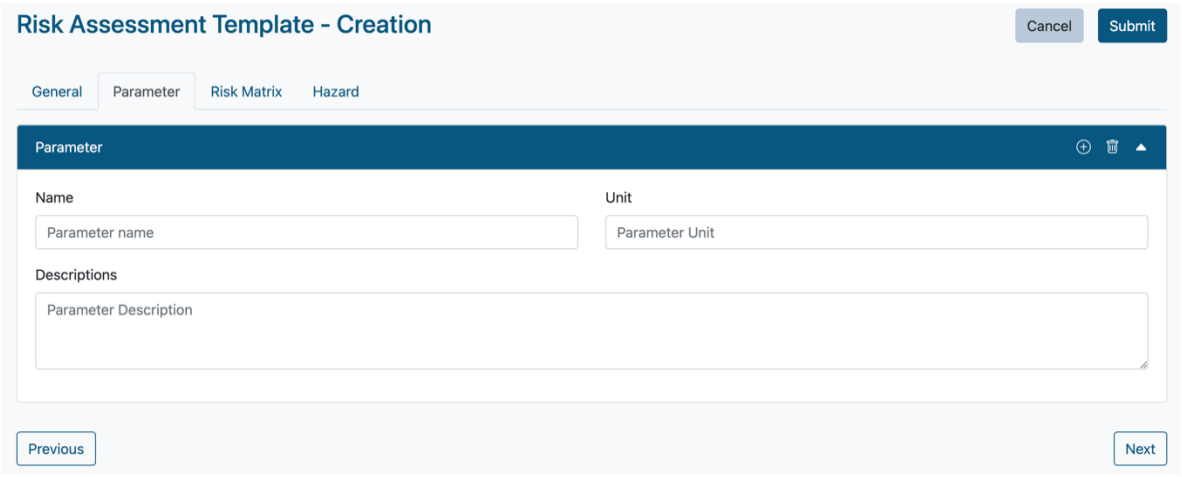

Figure 42 - Risk Assessment Creation Parameter tab

In the Risk Matrix tab (Figure 43) user can change the level of risk in the match between consequence and likelihood.

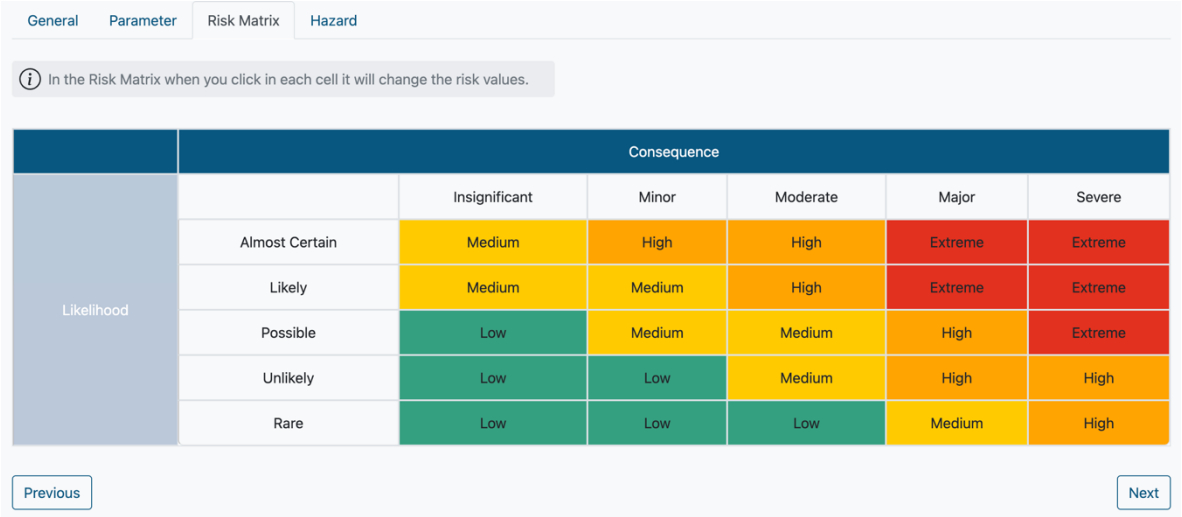

Figure 43 - Risk Assessment Creation Risk Matrix tab

In the “Hazard” tab (Figure 44) where the users have the possibility to create new hazard along with proposed control measures that will help to reduce the risk.

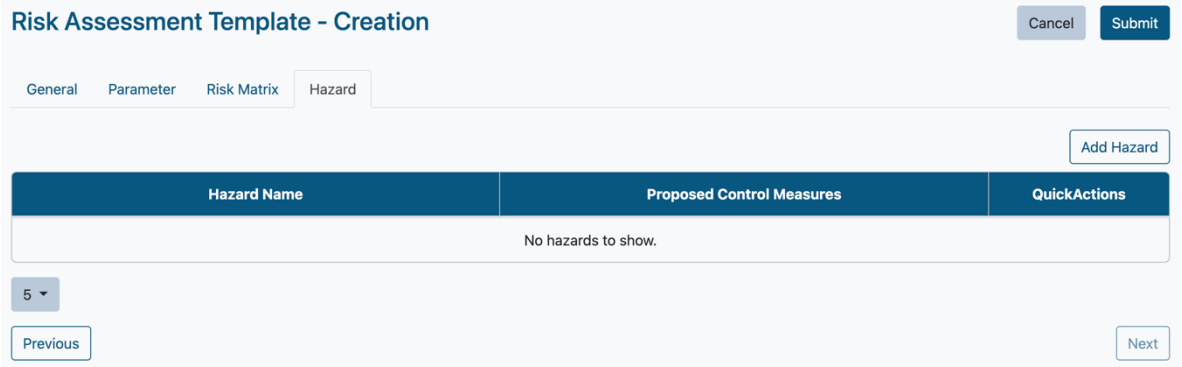

Figure 44 - Risk Assessment Creation Hazard tab

The hazard creation is divided in three parts:

- General, where it has information like name, description and section.
- Likelihood Rules, where it exists an interaction with the previous parameter created giving a rule name, choose the parameter, choose the operator (greater, equal, less) and the value.
- Proposed Control Measures are added filling up the name.

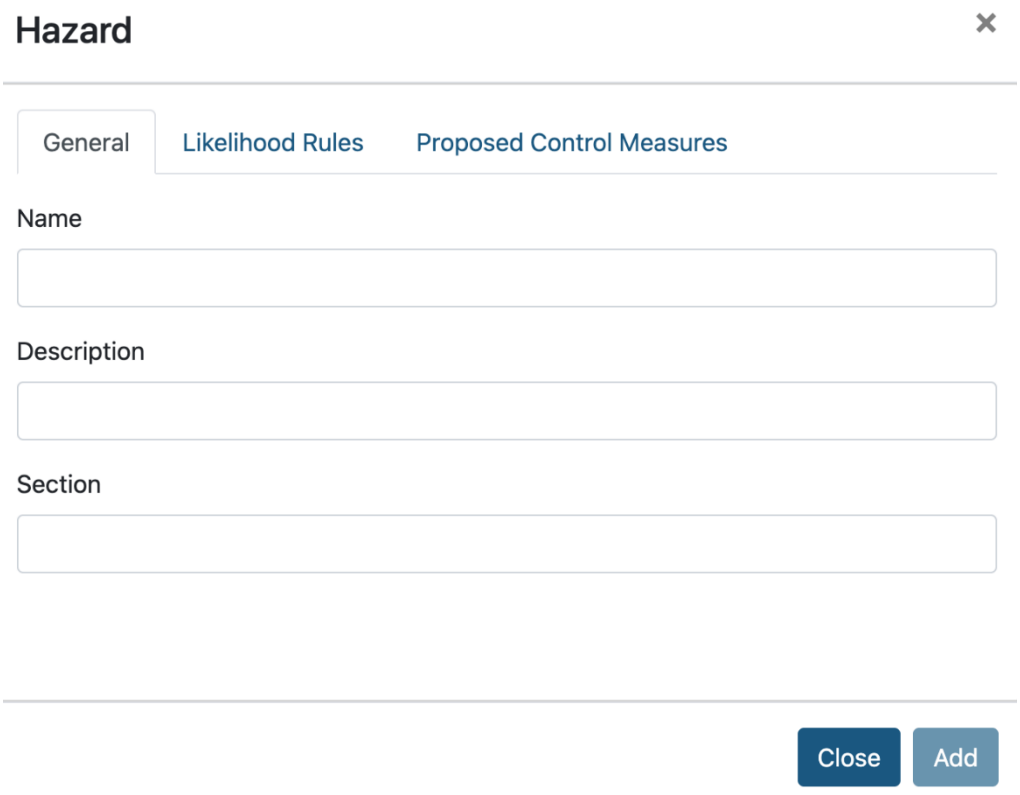

Figure 45 - Risk Assessment Creation Hazard tab adding (general tab)

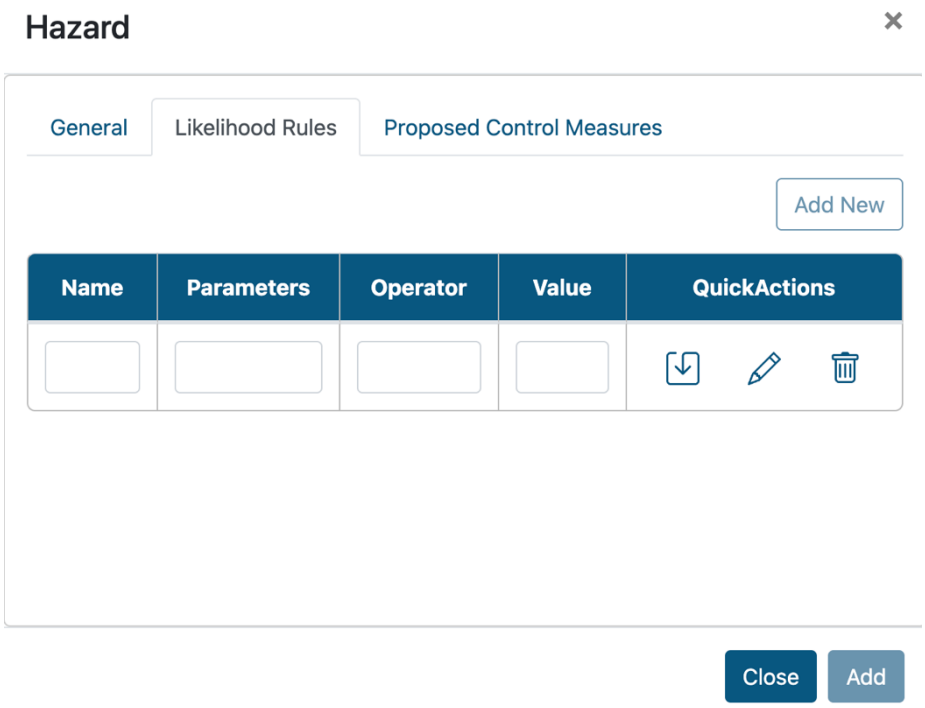

Figure 46 - Risk Assessment Creation Hazard tab adding (likelihood rules tab)

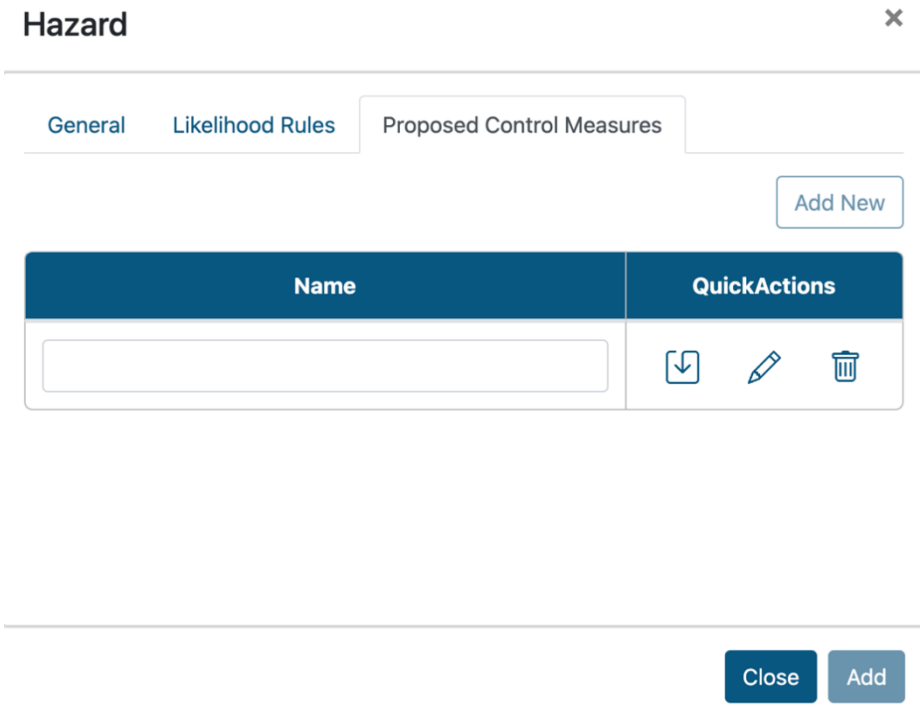

Figure 47 - Risk Assessment Creation Hazard tab adding (proposed control measures tab)

Figure 48 depicts the view where the list with all the Risk Assessment templates. In this view, there is the possibility to edit/view the existing ones.

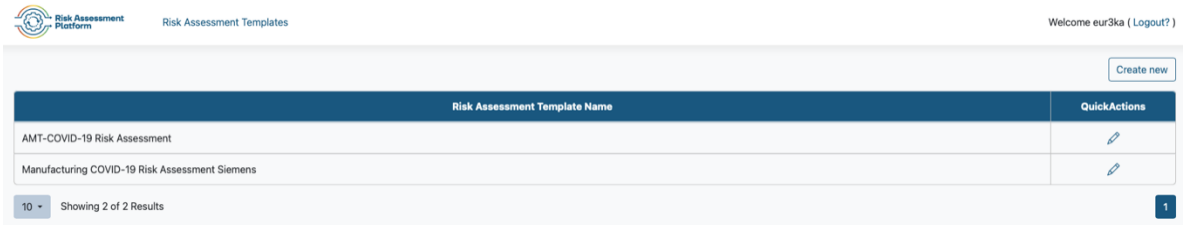

Figure 48 - Risk Assessment templates list

Editing/viewing it allows visualizing the status that was previously saved. It can be useful to continue to fill up to be ready to pass to the next intervening or fix any input that was incorrectly added.

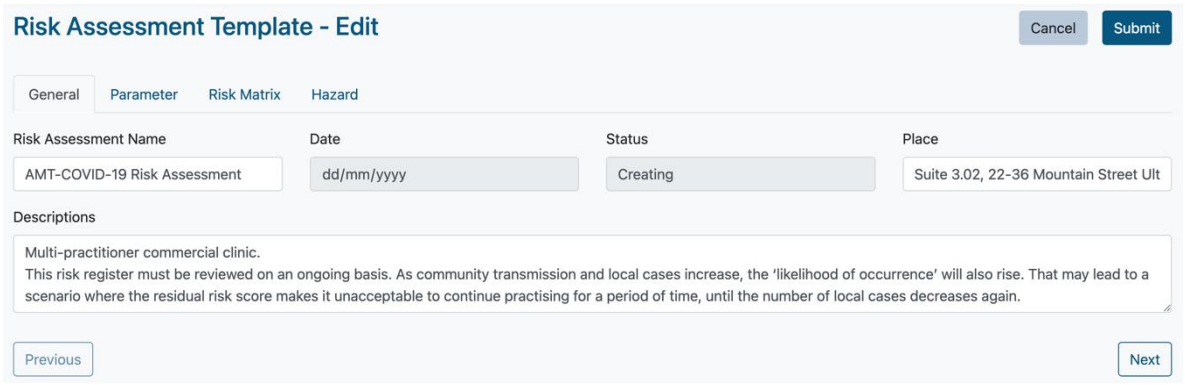

Figure 49 - Risk Assessment Edit/View

3 Pre-crisis Preparation

3.1 Supply Chain Transparency Services

Additive Manufacturing Network (AMN) has been designed and implemented to provide elasticity and speed in industrial users' relationships. Both buyers and suppliers are ensured to have access to a trusted design mechanism in terms of validation of ordered parts design via Siemens PLM platform.

Still, AMN got its own perspective of interaction before the crisis, given the context of industrial use. Mainly the assumption was to have AM (Additive Manufacturing) educated buyers who know what to order and how to analyse supplier's offers. COVID-19 crisis exposed some types of products, such as the spare parts for the medical infrastructure are less planned for the current production or their design is not known or available for suppliers on immediate demand. This leads to confusion, lack of trusted communication or capacity of a supplier to provide a meaningful evaluation of realisability.

Challenges identified have been considered by looking at some generic role personas as the ones on the following picture.

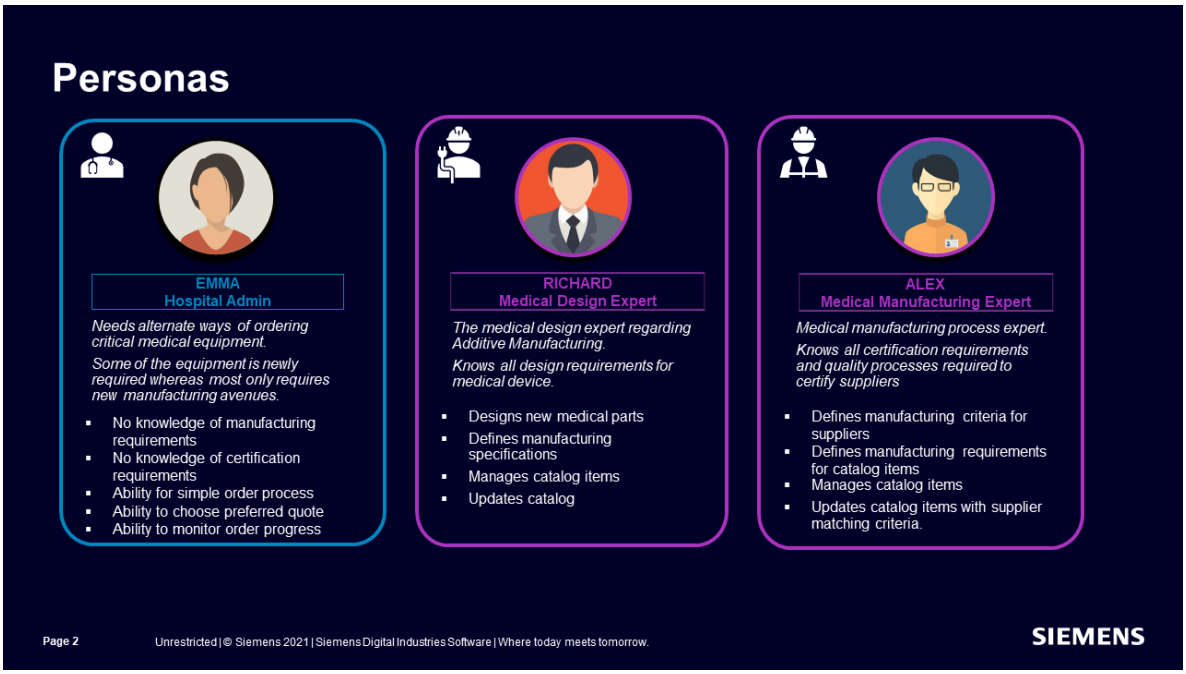

Figure 50 - AMN Roles

Those roles have been considered taking into account the aspects that crisis reveal overstress of medical teams and sudden need of specific parts, the very specific knowledge of medical equipment designers and the associated need for expert knowledge of manufacturing process.

It should be noted that AM leverage exactly the last aspect, it democratizes the access to highly specific manufacturing infrastructure for specialized designs that otherwise it could be very expensive to achieve.

Taking role by role AMN extended its availability and usability as follows:

- Hospital administrators, usually individuals without specialized education about technical restriction of equipment under use can have access to a specialized catalogue where parts of equipment are managed by certified designers. This limits the risk to order wrong or unknown components to not known suppliers, or not having the capacity to validate the capability to execute the order. AMN has developed a catalogue as an extension to existing capacity to validate suppliers capability and match them to validated design of part. For the hospital administrators this mechanism removes the risk of ordering wrong parts from untrusted suppliers.
- Medical design experts need to have a trusted mechanism to publish their certified designs towards the community. This is supported via a trusted connector towards the catalogue which is implemented in Mendix platform. This way the design is easily certifiable knowing the qualifications of designer, intended use and production restrictions. For the medical design experts catalogue and trusted connector represents a way to secure intellectual property and guarantee meaningful use of design produced.
- Medical Manufacturing Experts on the supplier side can complement catalogue entries with realisability criteria, this way being capable to accelerate safe and trusted ordering of parts. As observed the process is therefore enforced end to end simplifying the communication between the ones who need the certain element and the ones capable to delivery.

Here are few pictures relevant for the usability of catalogue.

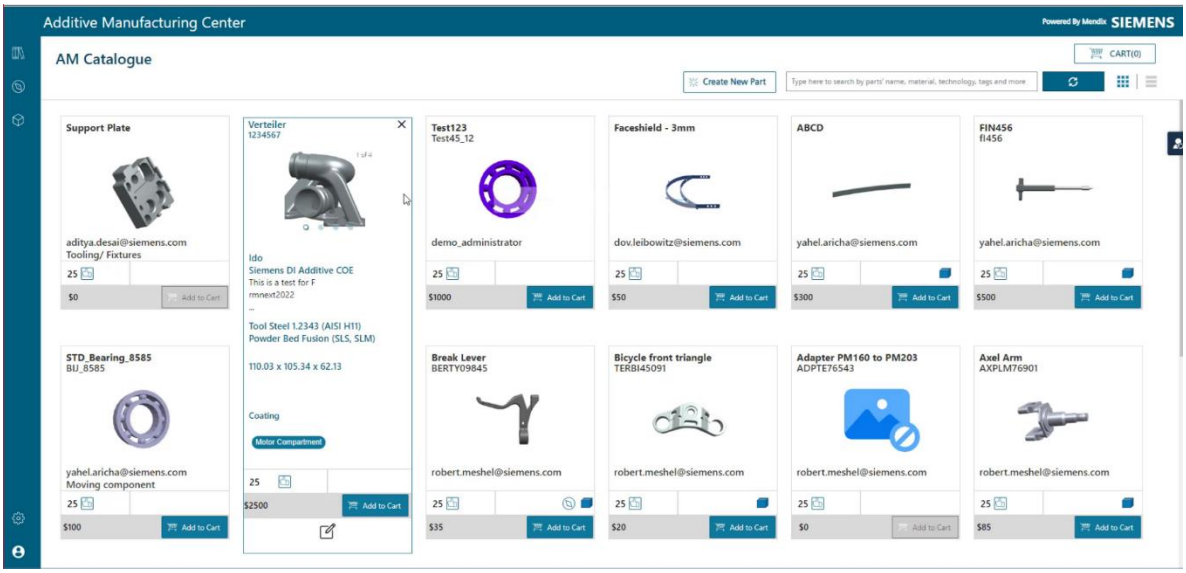

Figure 51 - AMN Catalogue general view

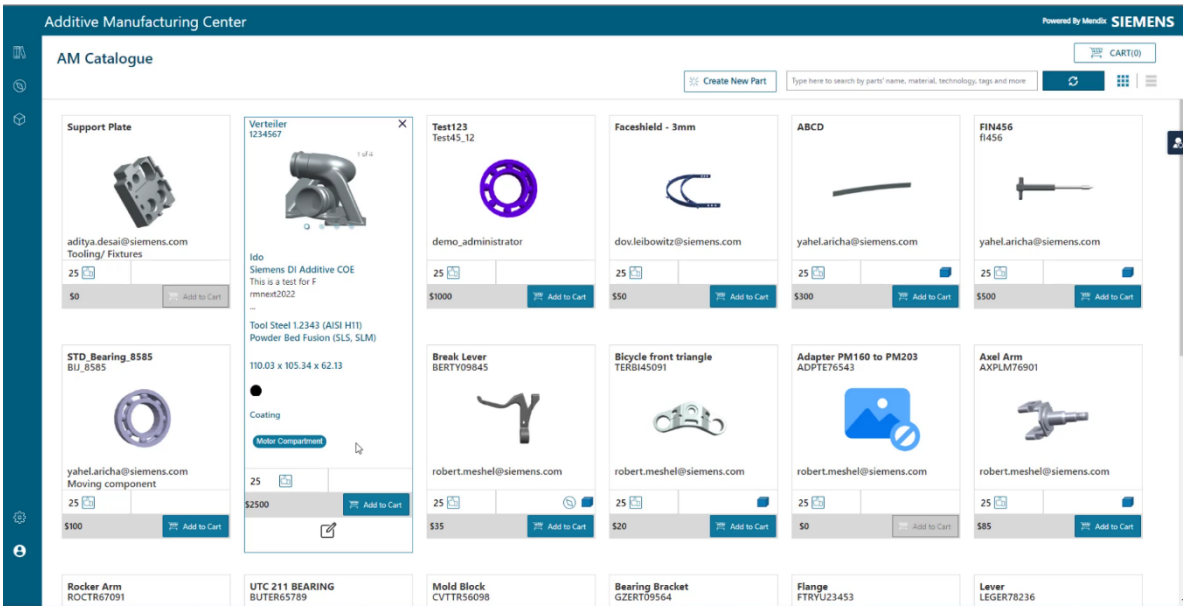

Figure 52 - AMN Catalogue part details

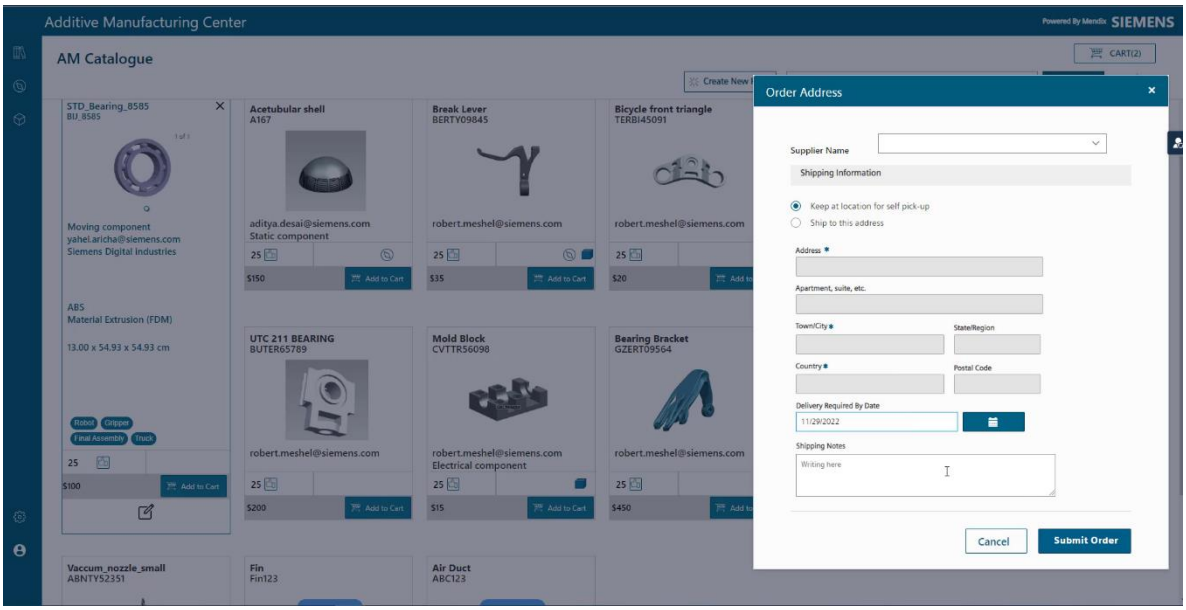

Figure 53 - Ordering process

Still, medical devices parts are not a common market for mass production and the is possible to not have access to all suppliers that can deliver. Even in this context the certified design is a valuable asset and can be used towards other platforms that can provide access to other potential suppliers. In this regard it is developed an AWS-based event service on which partner platforms can subscribe to receive requests for quotation based on trusted data.

Currently a proof-of-concept implementation is under development together with Fraunhofer partner, target being to prove the interoperability between AMN (Additive Manufacturing Network) and Smart Factory Web platform leads to the extended capability to generate matchmaking between requests based on certified design of assets and SFW managed suppliers.

3.2 Business Continuity Framework

3.2.1 COVID-19 Aware Shift Scheduling Service

To maintain business continuity during COVID-19 pandemic a smart shift allocation between staff workers can be applied to prevent infection spreading. The shift allocation is delivered as an autonomous software solution that includes a web UI for interactions with operators. The operators by using the web UI can define the production plant departments and assign employees and define their skills. The department can be further divided into sectors to ensure appropriate distancing between employees during a shift. Each department employee will be automatically assigned into sectors and shifts per sector according to their skills. Currently the tools support's 4 types of shifts: morning, afternoon, night and emergency shift. During the emergency shift there are available employees that can be selected in case of a contagious event to replace colleagues that might have been infected. Based on feedback collected for the second version of the tool two additional features have been added:

- A manufacturing line disruption, where an emergency disruption declaration form can be generated from the operator who can select an emergency event that can cause a manufacturing line disruption.
- An employee upskilling capability where the operator can define training programs which can be assigned among employees.

The Shift Scheduling software has been developed for the needs of Eur3ka project and has been applied in the SEAC pilot environment. Below the description of the different services, which have been applied to the pilot, can be found along with the software dependencies and installation instructions. Details for the platform specifications can be found in section 6.2 of D3.2 "Final Rapid Medical CCE/PPE Production Specifications & Eur3ka R3 Service Definition".

3.2.1.1 User Manual

3.2.1.1.1 Employee Management

The smart shift allocation system supports a personnel management user interfaced. The supported operations include:

- Employee insertion: A new employee is inserted into the system by defining his/her name, skills and the department to be assigned. Also, his/her availability to be assigned into shifts immediately is defined as working status. Employee update: An existing employee can be updated by correcting name, defining new skills, or changing the assigned department.

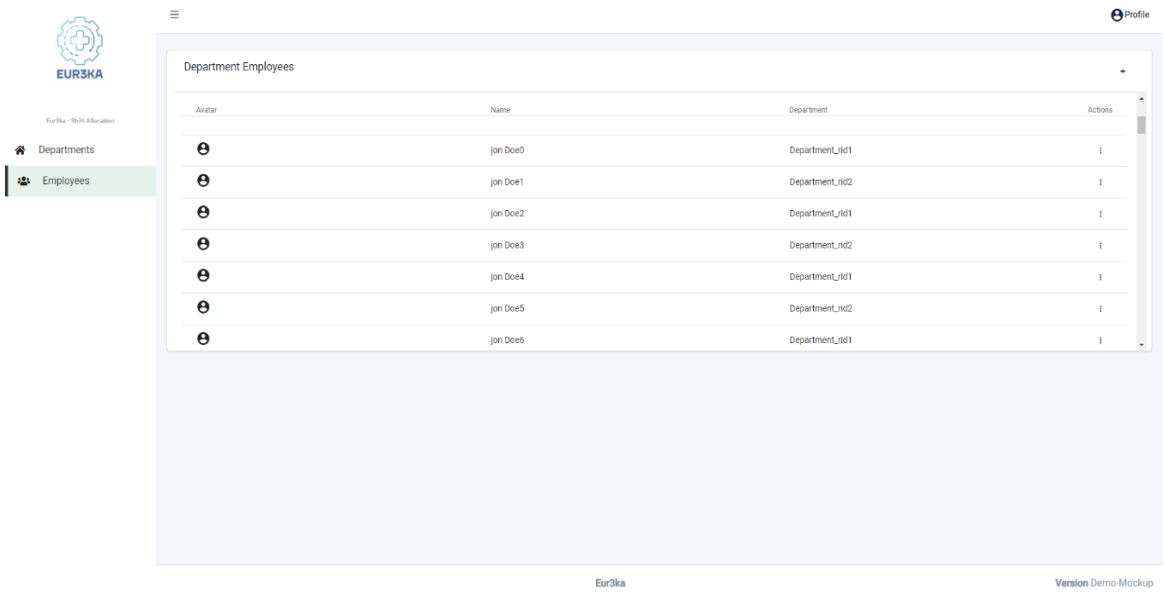

Figure 54 - Employees overview

In figures bellow the corresponding dialogues for inserting a new employee, updating his skills and department assignment are presented in forms of popup dialogues. The skills are a collection of strings that are inserted into the system according to the organization requirements.

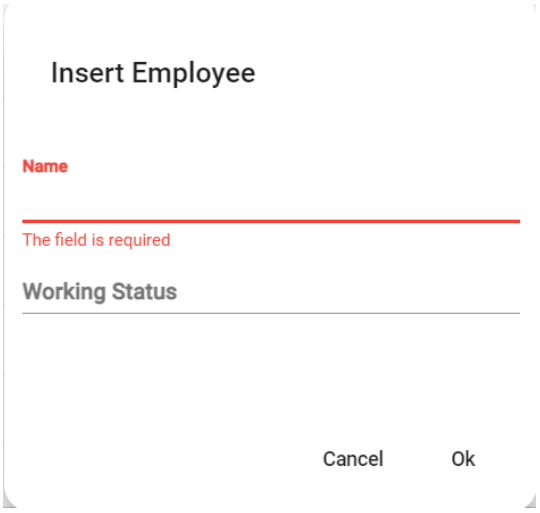

Figure 55 - Inserting a new employee

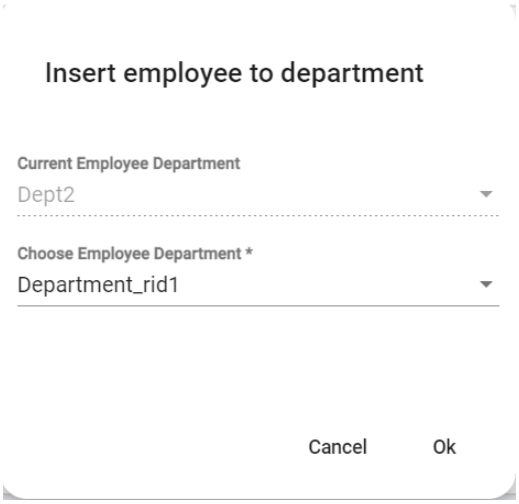

Figure 56 - Inserting employee to department

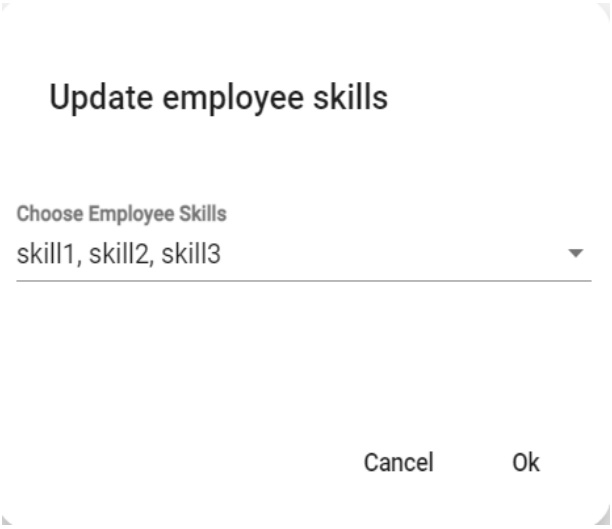

Figure 57 - Updating employee skills

3.2.1.1.2 Department Management

After inserting employees, the operator can inspect them in a vertical scroll-view as seen in Figure 58, in this scroll-view each department is visualized as a card having as information the department name, the number of assigned employees and the sectors that the department has been divided into. By pressing the **Add Department** button a new department can be inserted into the production plant by defining its name and the location if available.

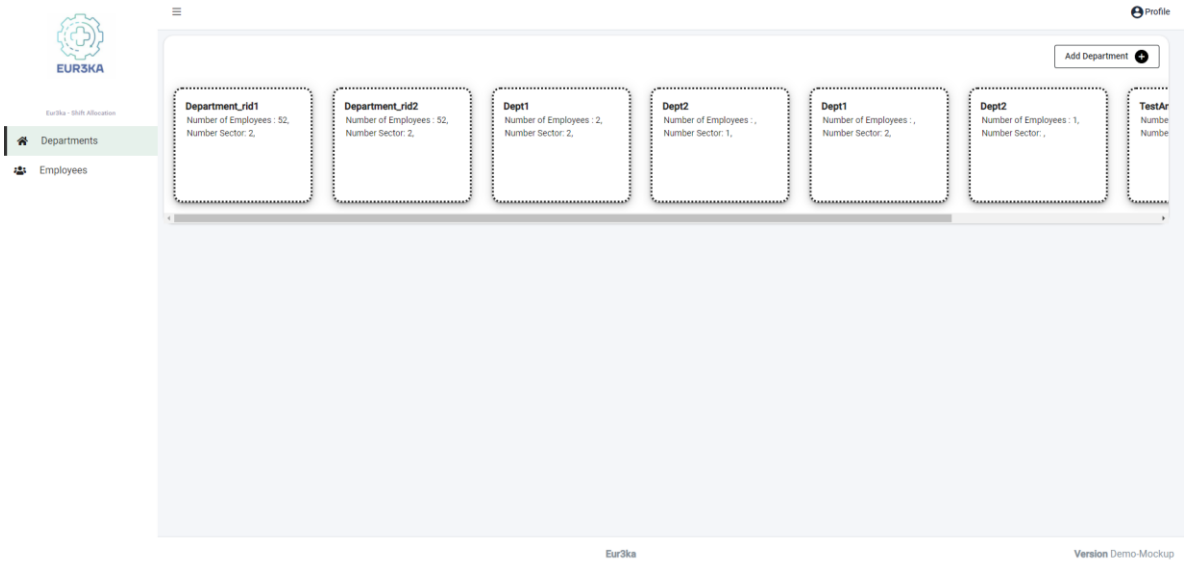

Figure 58 - Departments overview

By clicking upon a department then a redirection into a department page is performed. The department page includes department related information that include the number of assigned employees, the number of sectors and the number of COVID-19 incidents that have been reported in the specific department. Also, the individual lists of sectors and employees in the selected department is visualized. The operator can perform the following:

- Sector insertion: A new sector can be inserted to divide the department by defining its name and the maximum number of employees that can be assigned into the new sector shifts so that the COVID-19 precautions can be complied.
- Sector update: An already inserted sector can be updated, and the operator can define the set of skills that employees need to follow in order to be assigned into the corresponding shifts.
- Report insertion: The operator can report possible COVID-19 infections of the department personnel.

Shift Management: The operator can select to automatically assign department employees to shifts by selecting the commands from a dropdown menu. The command can be either to initialize the shifts or use the existing shifts which will be shifted automatically among employees and will be available from next week.

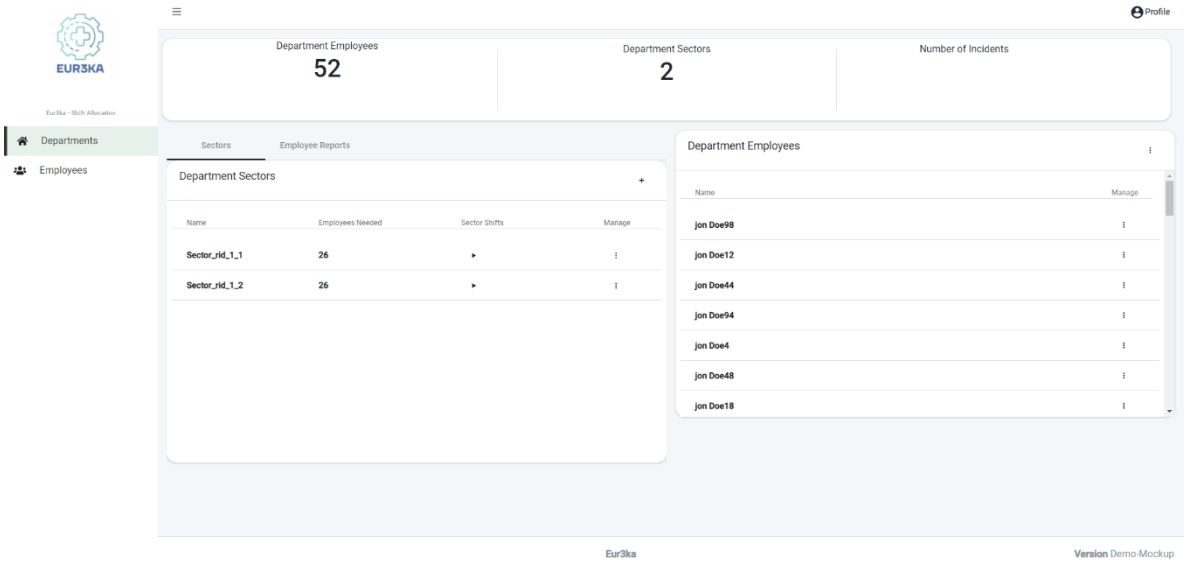

Figure 59 - Selected department overview

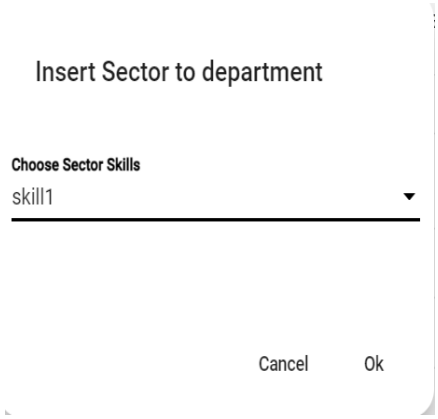

Figure 60 - Inserting skills that employees need to follow for the specific sector

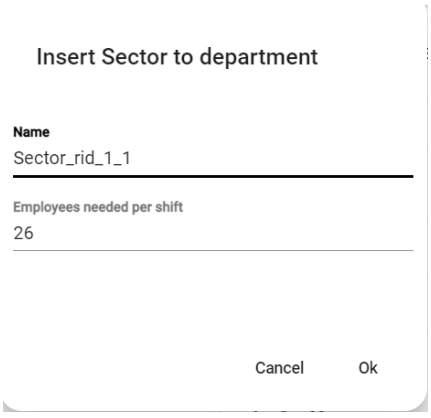

Figure 61 - Inserting new sector to department

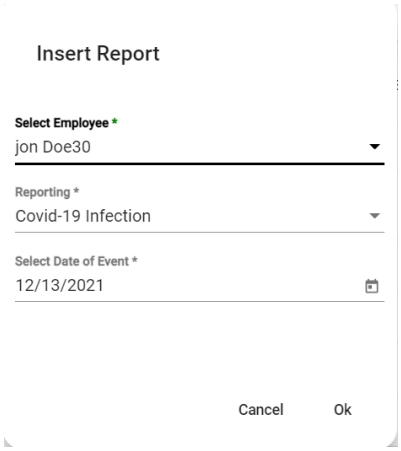

Figure 62 - Inserting COVID-19 related reports

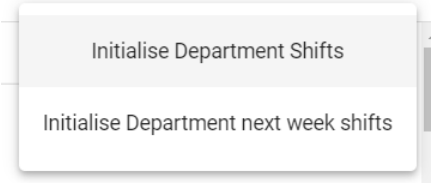

Figure 63 - Initializing shift allocation algorithm

3.2.1.1.3 Shifts Overview

By selecting a sector from a department, the operator can review the shifts automatically assigned by the tool in a form of an interactive timesheet per employee. The morning shifts are highlighted with green colour, the afternoon shifts are highlighted with orange, the night ones with blue and the emergency shifts are highlighted with red colour.

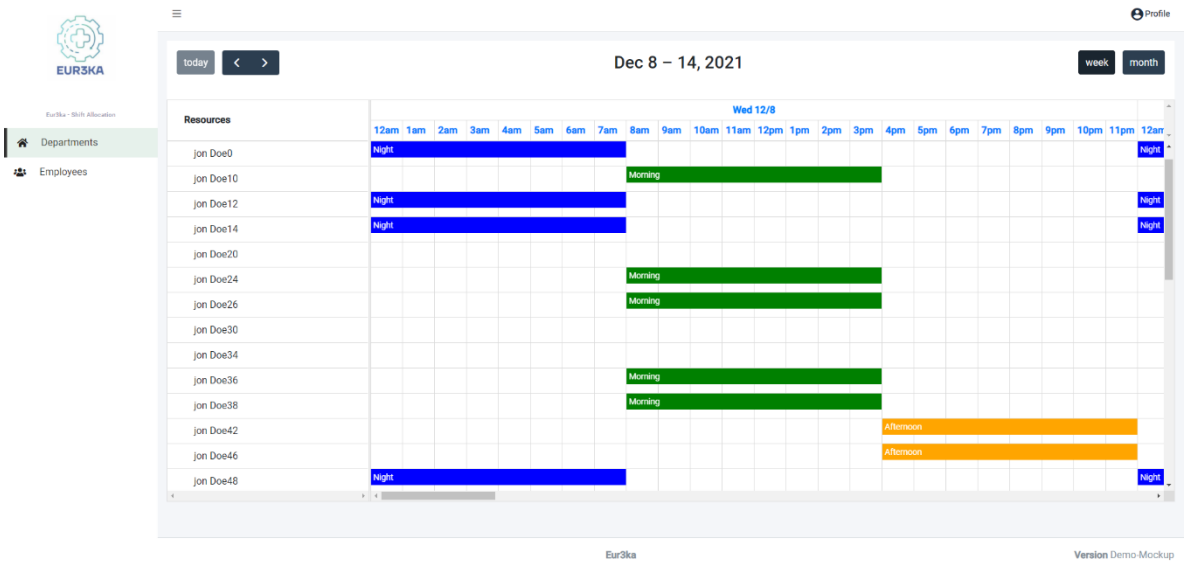

Figure 64 - Shifts plan overview per sector

3.2.1.1.4 Manufacturing line disruption

The Shift Scheduling enables an emergency manufacturing line disruption, which can be declared from an operator, for a specific shift, with a form that specifies an emergency event that can cause a manufacturing line disruption. The service enables the operator to:

- Select the shifts that will be affected (e.g. Morning, Afternoon etc.).
- To record the disruption reason which is persisted in the database.
- To mark the shifts back as operational by removing the emergency event.

In Figure 65 we can see an example of the emergency shift selection form.

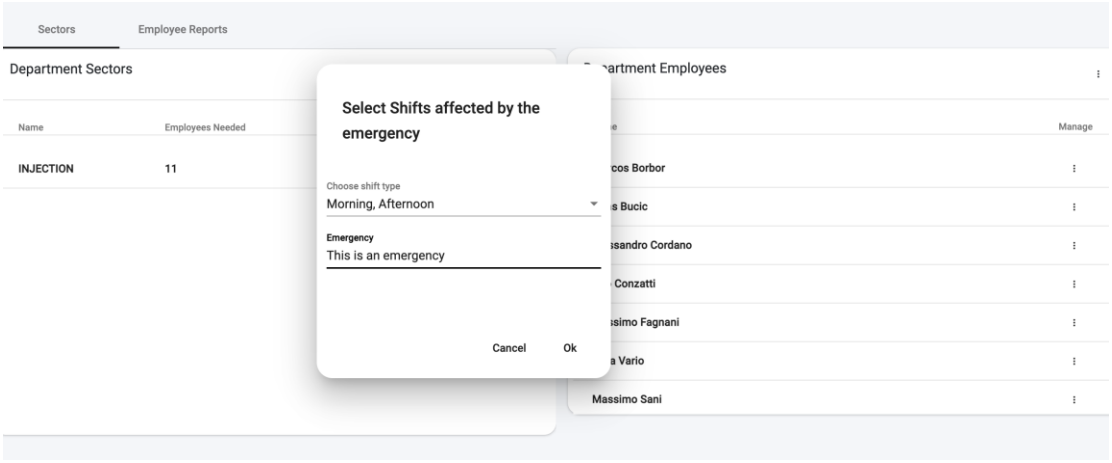

Figure 65 - Emergency shift selection form

In Figure 66 the emergency disruption visualization can be found where all affected shifts are marked in black label and at the bottom the disruption reason is presented.

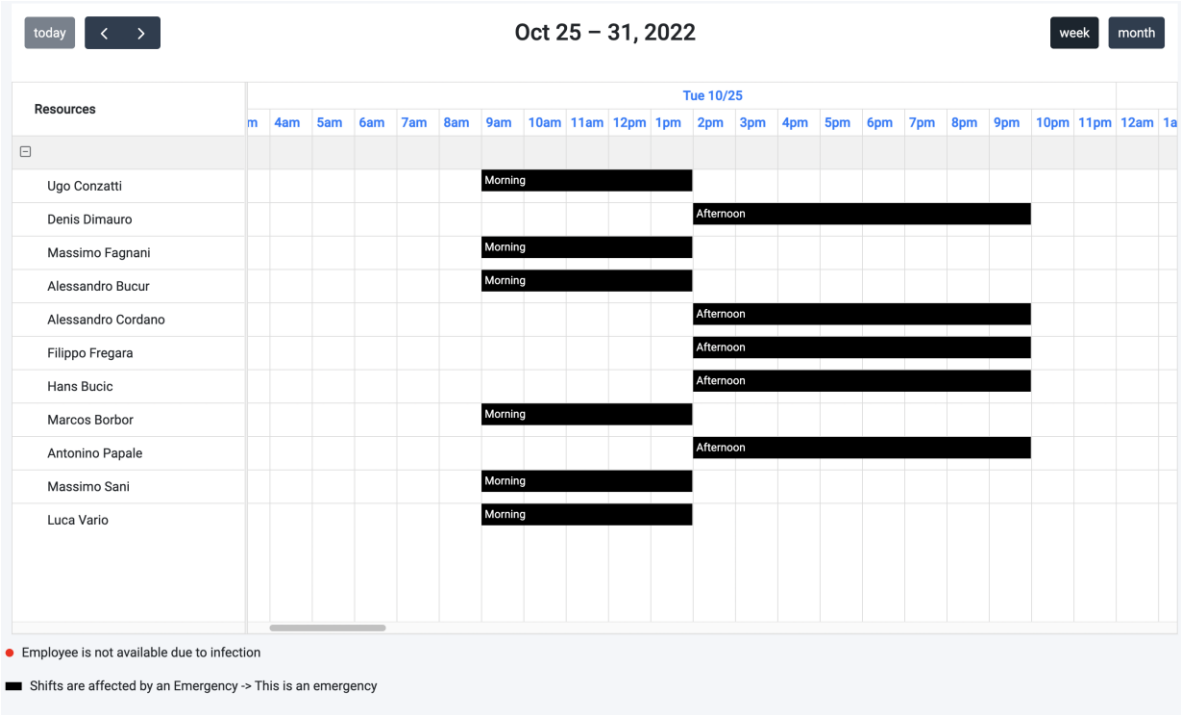

Figure 66 - Emergency disruption visualization

3.2.1.1.5 Employee upskilling

For the employee upskilling the Shift Scheduling service offers the capability to the operator to define training programs which can be assigned among employees. The service provides an interface to a database of trainings (with info on skills, programs, durations etc.) that can

be linked to the employees and their qualification. The employee upskilling information that can be recorded is shown in Figure 67 in the entities and their relationships that are persisted.

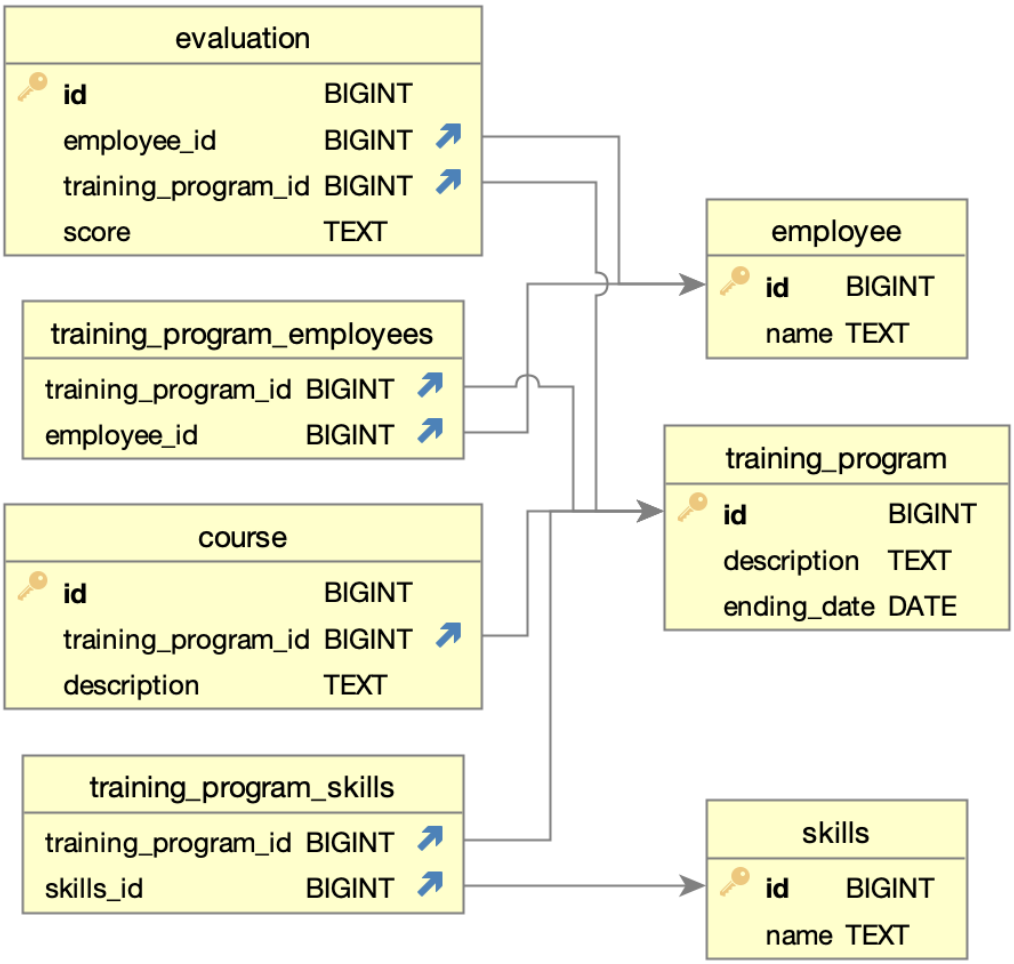

Figure 67 - Employee upskilling entities

Each training program consists of multiple courses and can be attended by multiple employees. Upon completion the employees attended per training program can be evaluated. If the evaluation reaches the required threshold (e.g., 70%), then the skills provided by the training program are automatically assigned to each employee that has completed with success. The shift allocation module then can be triggered to reassign production line shifts based on the updated employee skill set.

3.2.1.2 Installation

The shift allocation is delivered as a service and can be hosted in any cloud provider as it consists of multiple components that can be deployed independently using docker-compose scripts. The installation process is automated using the Gitlab CI/CD [1] pipelines building the software directly from version control, publishing images and making the deployments to the

[1] https://docs.gitlab.com/ee/ci/

cloud provider virtual machines. The shift allocation solution consists of multiple software components that are developed under different technologies and frameworks and are separated into 3 layers which implement the frontend the backend and the algorithm respectively:

- Frontend: The frontend software component is developed under Angular framework[2] and implements the logic that is presented in the previous section.
- Backend: The backend software component is developed under spring boot[3] framework and is responsible for providing data to the frontend and by exposing the following Rest APIS. The API documentation is available in the link bellow:

  https://eur3ka.shift-allocation.rid-intrasoft.eu/api/swagger-ui.html#/

Table 2 - Rest APIS Descriptions

REST interface	Description
/employees	Interface for inserting and retrieving new employees to the system, distribute them to departments and assign roles.
/sectors	Interface for retrieving sectors per department and inserting new ones to an existing department
/roles	Interface for, inserting and retrieving roles as discrete instances.
/reports	Interface for letting employees post events regarding any COVID-19 incident and their availability to work.
/shifts	Interface for inserting and retrieving new weekly shifts per department sector.
/training-program	Interface for inserting Creating Training Programs that can lead to certain skills upon accomplishment. A training program consists of multiple courses and can participate various employees.
/evaluation	Interface for accessing each training program evaluation. Upon completion the evaluation per employee is available.
/courses	Interface for accessing courses assigned to each training program

- Algorithm: The algorithm software component is developed in Python programming language and is implementing the formulation and execution of the shift allocation problem. The algorithm provides Linear programming solutions by considering the following constraints:
  - Each employee must be assigned to exactly one shift and one sector
  - Each employee must work in exactly one sector per shift
  - Ensures that each employee that is selected for a specific shift is aligned with the sectors required qualifications. Employees are selected according to their skills and the way they match with the sector's skill requirements. All shifts

[2] https://angular.io/guide/architecture
[3] https://spring.io/projects/spring-boot

are 8-hour long by default but can be adapted according to the organization's time plan.

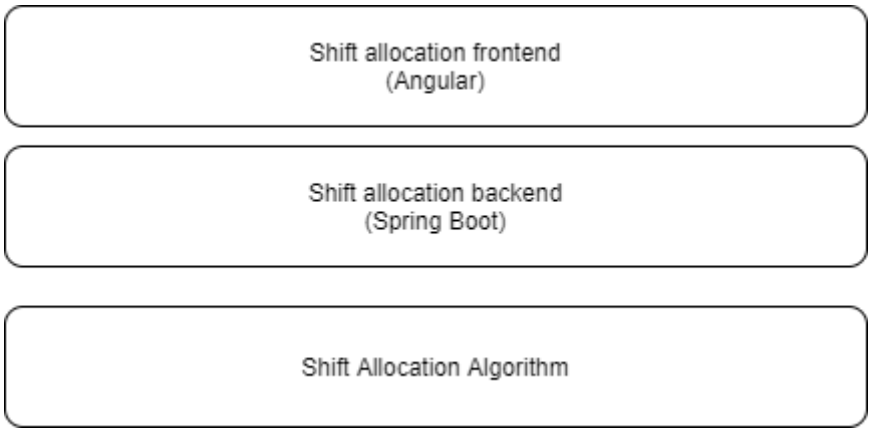

Figure 68 - Software components stack

The installation process is triggered by the CI/CD pipeline which includes the following steps:

- Build process: The process can be triggered manually or automatically if the source code is updated on GitLab version control. It performs automatically building, packaging and containerization of all components by downloading dependencies and third-party libraries. The process is tagged with the **build-job** acronym.

Publishing software process: The process is triggered after the successful build of the previous step and is responsible for transferring and deploying the executables to the cloud provider. The publish process is tagged with the acronym **publish-job.**

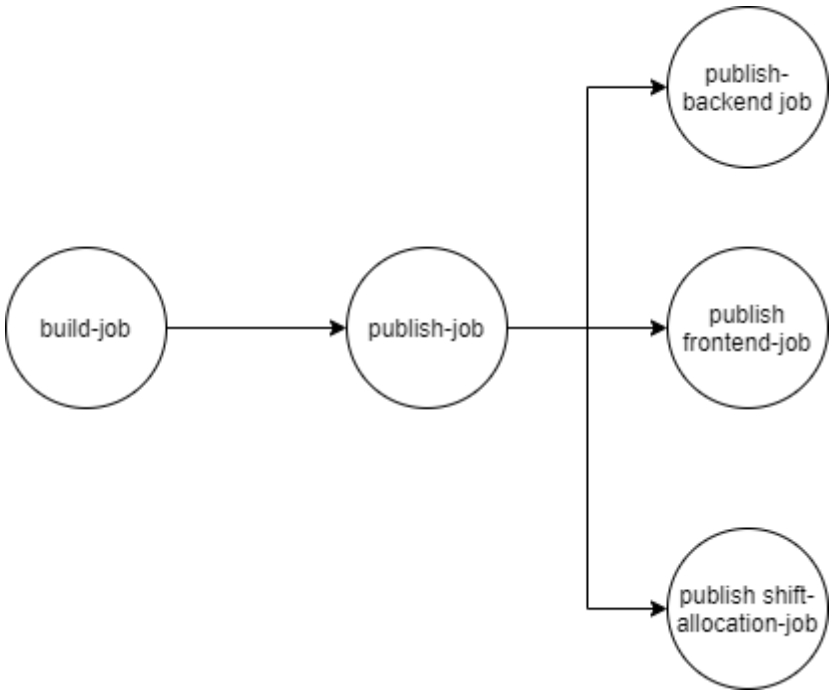

Figure 69 - CI/CD pipeline

- and is divided into subtasks for publishing the frontend the backend and the algorithm software components. The subtasks are tagged with the acronyms **publish-backend job publish frontend-job** and **publish shift-allocation job** respectively.

Each CI/CD pipeline step in order to build the individual software components is executing the docker-compose scripts define in the table below. The source code of the whole solution is available:

https://gitlab.com/intrasoft-rid-eur3ka/T4.6

Software Component	Installation Script

Frontend	`version: '3'`
	
	`#networks:`
	`#monitor-net:`
	`# driver: bridge`
	
	`services:`
	
	`  eur3ka-dashboard:`
	`    pull_policy: always`
	`    networks:`
	`      - backend_api_network`
	`    environment:`
	`      - SHIFTS_WEB_SERVICE_URL=https://eur3ka.shift-allocation.rid-intrasoft.eu/api`
	`      - SHIFTS_SOCKET_SERVICE_URL=https://eur3ka.shift-allocation.rid-intrasoft.eu`
	`    build: .`
	`    image: eur3ka-dashboard`
	`    container_name: eur3ka-shifts-dashboard`
	`    restart: always`
	`    ports:`
	`        - 4000:80/tcp`
	`networks:`
	`  backend_api_network:`
	`   external: true`

Backend	`version: '3'`
	
	`services:`
	`  ShiftsServer:`
	`    networks:`
	`     - postgres_postgres`
	`     - api_network`
	`     - kafka_default`
	`    build: .`
	`    image: eur3ka-shifts:latest`
	`    restart: unless-stopped`
	`    container_name: eur3ka-shifts-service`
	`    environment:`
	`       - spring.profiles.active=prod`
	`       - spring.jpa.hibernate.ddl-auto=update`

	- spring.datasource.url=jdbc:postgresql://postgres:5432/shifts - spring.datasource.username=postgres - spring.datasource.password=rebecca - kafka.ip=kafka - kafka.port=9092 ports: - 8081:8081/tcp networks: postgres_postgres: external: true kafka_default: external: true api_network: driver: bridge
Algorithm	version: '3' services: optimizationalgorithm: networks: - kafka_default image: optimizationalgorithm:latest container_name: optimization_service build: . environment: - kafka_ip=kafka networks: kafka_default: external: true

Table 3 - Software components installation scripts

3.2.2 Virtual Training and Remote Support

During the implementation of the SVM pilot two lines have been further developed by using the digital twin, the virtual training, and the remote support. Visual Components 4.0 provides a VR interface that used in combination with Visual Components Experience enables the utilization of the most common VR headsets in the market to provide a 3D virtual experience and visualize the simulation and digital twins developed within Eur3ka.

Furthermore, VC Experience deploys a 3D visualization tool to be used in PC and mobile devices, offering high level visualization when there is not availability of VR equipment. In addition, this functionality has been become very useful for documentation purposes of the system, as it can be embedded in a web interface.

From the Eur3ka development this functionality has become as a documentation tool to facilitate the digital continuity of the development information and made it available to the different stakeholders of the production system. The information is stored at different levels of granularity ensuring that the operators get the training information and the maintenance personnel the support and maintenance datasets.

During the development of the project, it has been identified that each customer has different training requirements for their operators. The virtual model allows to compile the full datasets, but at the end is each production owner who defines the operational models, and the information is made accessible to the operators according to the operational protocols of each factory and production line.

The remote support has been tested within the project testing the support of teams at different geographical areas. During the commissioning of the pilot line for demonstration purposes two use cases were validated, runtime support and discontinued support.

Discontinued support was tested for validating responding of teams located in different time zones. This remote support was targeting the reconfiguration and problem solving, while the production line was out of production, ensuring that the programming and validation of the production schemes were ready for ramp up when the production shift started. Runtime support was tested while machine operation, allowing on site and remote teams to cooperate to solve production problems.

Both use cases were successfully tested and validated.

3.3 Flexible Production Line Design

The Eur3ka ontology will serve as a common vocabulary throughout all the trials. This will ensure that each term used has a specific meaning and all Eur3ka applications are aligned and can operate without communication issues. There are two different ways that the Eur3ka ontology can be utilized during the trials and after the trials. Pilots and technology providers can use the ontology and extract all the defined relations that each term has which will help them understand and enrich their models, technologies, and their use cases. One of the benefits of ontology design is that reveals links and relations between different terms that are not obvious and therefore new actions can be made to satisfy those new needs. Furthermore, the use of the Eur3ka ontology is a closed loop process, meaning that Pilots and technology providers will use the ontology and as they understand more about their process provide feedback for the enrichment of the Eur3ka ontology. The second use of the Eur3ka ontology is to be used as an intermediate layer between Eur3ka applications and data. This will increase the interoperability of the Eur3ka platform and at the same time as the platform is used and data are collected, valuable knowledge and be extracted and help improve the platform.

As a Design Rationale (DR), ontology can be used as follows [1]:

- Level 1: Used as a common vocabulary for communication among distributed agents.
- Level 2: Used as a conceptual schema of a relational database. Structural information of concepts and relations among them is used. Conceptualization in a database is nothing other than conceptual schema. Data retrieval from a database is easily done when there is an agreement on its conceptual schema.
- Level 3: Used as the backbone information for a user of a certain knowledge base. Levels higher than this play role of the ontology, which has something to do with "content".
- Level 4: Used for answering competence questions.
- Level 5: Standardization

  - Standardization of terminology (at the same level of Level 1)
  - Standardization of meaning of concepts
  - Standardization of components of target objects (domain ontology).
  - Standardization of components of tasks (task ontology)
- Level 6: Used for transformation of databases considering the differences of the meaning of conceptual schema. This requires not only the structural transformation but also semantic transformation.
- Level 7: Used for reusing knowledge of a knowledge base using DR information.
- Level 8: Used for reorganizing a knowledge base based on DR information.

The detailed ontology description can be found in deliverables 2.2 and 3.2. The figure below is an extract from the Eur3ka ontology which presents the core classes of the developed ontology. Those classes are the foundation of the developed data models that will be presented in the upcoming sections.

Below are following the core Eur3ka classes:

- Eur3ka network actor
- Distribution network
- Asset
- Human resource
- Product
- Customer order
- Supplier
- Manufacturer
- Manufacturing process
- Manufacturing material

3.3.1 Re-use of Reference data models

In literature a series of data models have been developed focusing on different periods of product lifecycle. One of them is closely related to Eur3ka scenario and could greatly facilitate the development of Eur3ka data models. Our future models will be based on these existing models with some additions for serving better the needs of Eur3ka platform.

3.3.1.1 MPFQ model

The MPFQ-model is named after its four main elements: Material (M), Production Process (P), Product Functions/Features (F), Product Quality (Q). This model was developed as part of the EU-project "inteGration of pRocess and quAlity Control using multiagent technologies (GRACE)" (GRACE consortium 2011). This model focuses on the manufacturing phase of the product while considering the strong interactions between product design and plant planning. At the manufacturing phase the planned product quality is brought into reality by assembling procured materials within production processes. The final product produced satisfies or dissatisfies the customer requirements and is being sold on the market. The roles of different elements of the model are illustrated in Figure 70 [2].

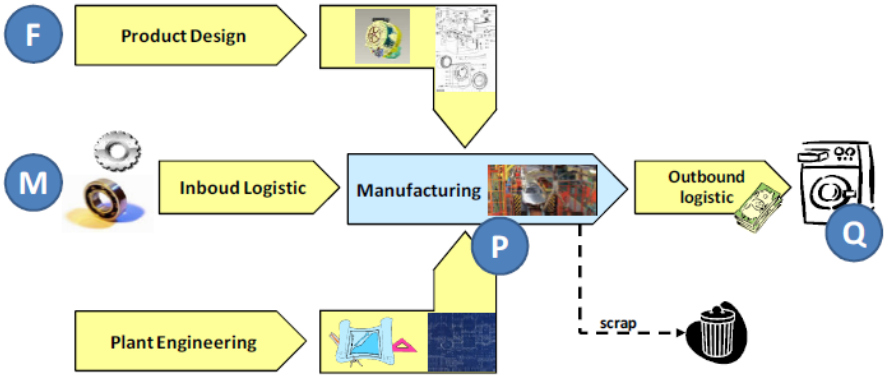

Figure 70 - Central role of manufacturing for product quality

The definition of the four elements of the MPFQ-model is:

- **Material (M)** - as a collective term for everything that is needed to produce a certain product or product component. This may include raw materials (Oxford English Dictionary 2012b), pre-products, consumables (Oxford English Dictionary 2012a), operating supplies, product components and assemblies.
- **Production Processes (P)** - processing and transforming materials into the final goods by using machines, tools and human labour. This process is defined within the plant engineering. (DIN 8580),
- **Product Functions / Features (F)** - as distinguished characteristics of a product item. This is mostly focused on functionalities like specific tasks, actions or processes the product is able to perform, but may also include other features like performance, etc,
- **Product Quality (Q)** - measured, following (DIN EN ISO 9000), as the degree of conformance of final product functions and features to customer requirements.

Figure 70 depicts the four main elements of the MPFQ-model and their interrelations. Within the MPFQ-model two types of interrelations can be found: the recursive dependencies between materials processes and functions and the straightforward dependencies of the MPF-part to the quality.

Starting with a manufacturing process (P) typically two or more materials (M) are combined to form a function (F) (see blue arrows in Figure 70). A Function is usually formed by one material acting on another (orange arrows in Figure 70). Hence, there is a closed interrelation loop given within the MPF-part. This fact is not surprising, as it shows the strong interlocking of plant engineering (combining materials (M) in production processes (P)) and product design (defining product functions (F) realized by materials (M)).

According to (DIN EN ISO 9000), product quality can be defined as conformance of product functions to customer requirements. Thus, product quality is an aggregation of one or more product functions/features (black arrows in Figure 70). Despite these primary dependencies there are also processes and materials defining the product quality (black dashed line in Figure 70). This can be easily seen by taking the example of a green product footprint, which is e.g. depending on the energy consumption of the product and the resources spent during the manufacturing of the product. Thus, taking the example of a washing machine, the motor

and heating element (materials) and the energy consumed during the single production processes primarily define the green footprint quality of the product.

4 Crisis Response

4.1 Eur3ka Certified Assets Catalogue

AMN Catalogue has been designed based on an observation of the crisis behaviour exposed by different types of actors during the initial phases of the COVID-19 crisis. One of the observed relevant issues those days was related to the scalability of production of key medical parts with a low number of producers in the market.

The second visible issue is related to the availability of validated designs for the potential additive manufacturing producers, altogether with constraints related to materials and delivery.

The third issue observed was that the additive manufacturing market is rather specialized by industry type served. Therefore affiliated suppliers tend to be oriented to answer the requests of certain customers.

The COVID-19 crisis forced all those actors to reconsider their capability to respond towards a market with multiple simultaneous hard constraints, including low technical educated buyers who still need access to trusted designs and suppliers.

AMN Catalogue has been developed in two steps. The first one was designated to experience the capability of Mendix, a low-code Siemens platform to quickly integrate with Data Spaces concept and connect with processes established by AMN for the relationship between buyers and suppliers. This step aimed to validate the flow between orders received via a trusted connector towards an API developed by AMN to receive well-formatted orders. The role of the catalogue, in this case, is to guarantee that only certified designs are registered, connected with knowledgeable suppliers and available to be ordered. After this step, all the processes of pricing, ordering and delivery can be done via AMN functionalities as before.

The second development loop took into account a re-implementation of the catalogue as a full Mendix service, allowing direct exploration of parts based on their intended use, type of materials available to implement a certain geometry and seamless access to suppliers' matchmaking service, including quotation.

In addition, it was implemented and made available an SQS AWS message service allowing third party extension of suppliers search towards peer platforms. This is also a consistent step towards resilience and increased access of non-technical buyers to extended supply chains.

The following images are reflected a few relevant functionalities of the catalogue.

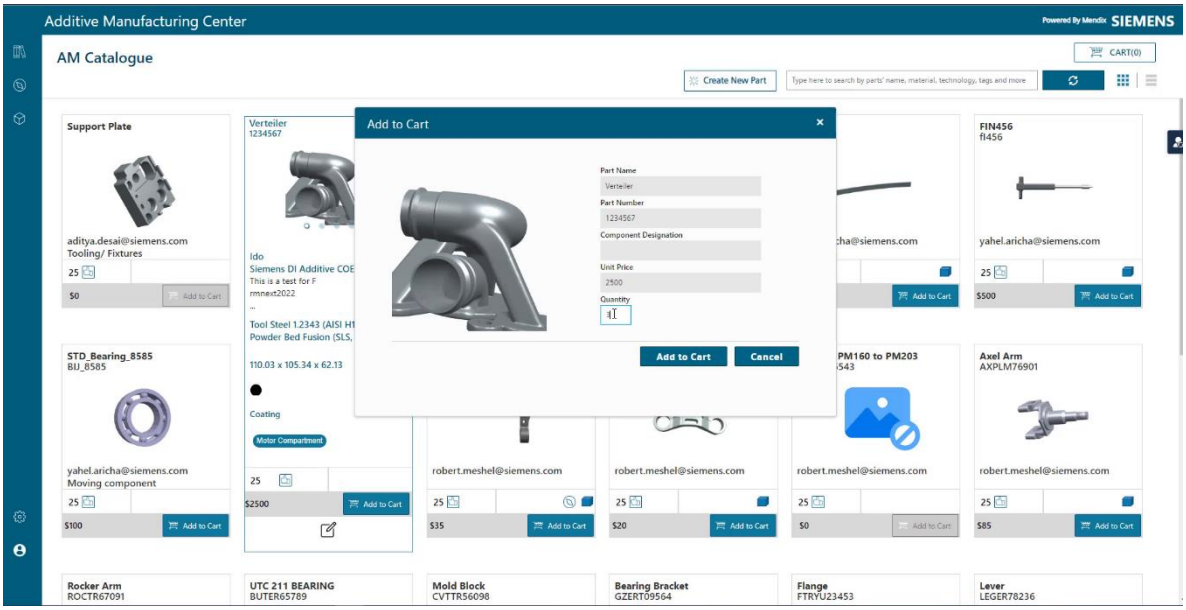

Figure 71 - Easy ordering of certified designs

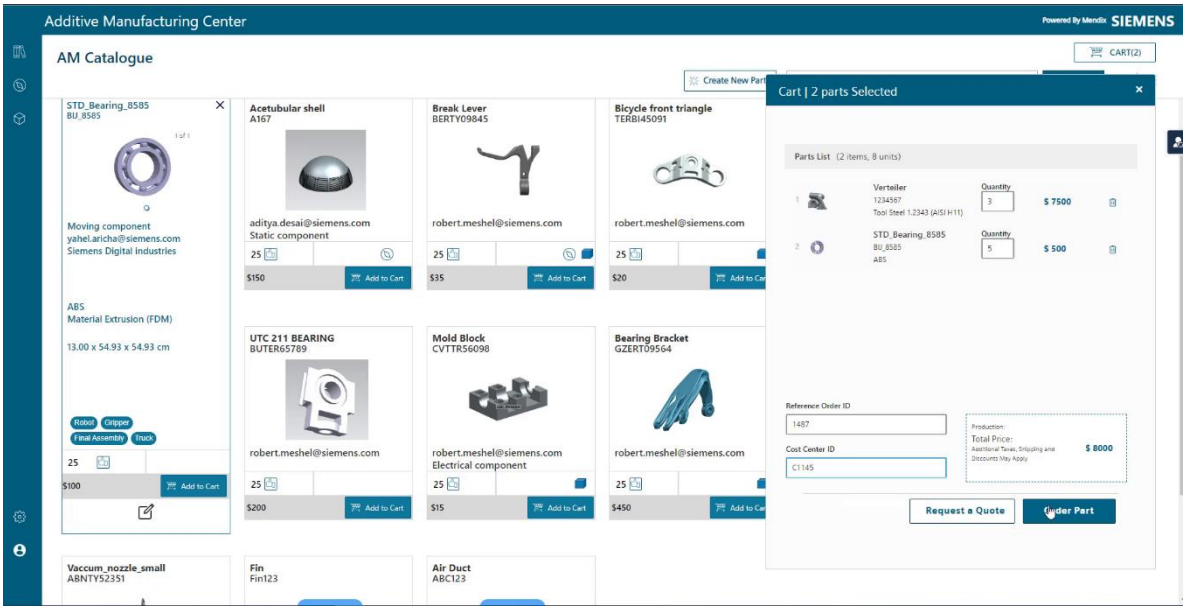

Figure 72 - Integrated ordering process in the catalogue

4.2 Smart Mediation & Matching Services

The Smart Matching and Mediation Application (SMMA) is a web service with an HTTP REST interface. It filters and sorts a given list of supply chains based on constraints specified in the request. For this purpose, it fetches sensitive data directly from the factories and handles the data in a trusted manner. The modular design allows easy integration of new constraints and sorting algorithms. This chapter describes the results of the final version and the changes made since D4.3.

4.2.1 Moving from Dataspace Connector to Eclipse Dataspace Connector

To ensure the sovereignty of sensitive data, the SMMA uses the concept of the Industrial Data Space (IDS) and its IDS connectors. The initial version of the SMMA documented in D4.3 was based on the Data Space Connector (DSC). However, all development resources from the DSC project are shifted to the Eclipse Dataspace Connector (EDC)[4]. The EDC will implement the IDS standard as well as relevant requirements for Gaia-X or Catena-X.[5][6] Since the EDC has an open structure and is specially designed to integrate extensions, it is easily extendible for other dataspaces. To enable a wider range of interoperability in the future, the SMMA implementation switched from the DSC to the EDC. To enable the integration of the EDC, it was necessary to update the architecture of the SMMA and implement additional components.

Since the factory constraints are provided via an Asset Administration Shell (AAS) model, the EDC on side of a factory needs to provide the data elements of this AAS model. Furthermore, each element within the AAS model needs to be represented as an EDC asset. To avoid the high manual effort, an extension for the EDC was developed in another project to enable the easy use of AAS models within the EDC.[7] In this project, this extension is used to provide the AAS model, which contains the sensitive data of the factory, via the EDC.

4.2.2 Updates on Architecture

The concrete implementation of the architecture described in D4.3 and the switch from DSC to EDC revealed the need for extensions to the architecture of the SMMA. In this section, the updates of the architecture are described. The updated architecture is shown in Figure 73.

Following new sub-/components were added to the architecture:

- **Configuration**: To improve usability, the SMMA can be configured by providing a configuration file.
- **MetaDataManager**: The result set contains some information about the factory accessibility or the fulfilment of the required constraints.
- **Constraint Parser**: An AAS constraint template (see section 4.2.4) provided by the factories needs to be parsed to get the actual data from the factories.
- **EDC Adapter**: Since there are several implementations of the IDS standard, the SMMA is designed to support different IDS connectors. An adapter interface needs to be implemented for each IDS connector, enabling the SMMA to communicate with the specific IDS connector. The EDC Adapter is a default implementation of this interface.
- **RatingAlgorithm:** To be able to sort supply chains according to the fulfilment of the user-defined constraints, this component calculates a rating value for each supply chain based on the required and actual constraint values.
- **SortingManager:** This component sorts the supply chain set by their rating values.

[4] https://projects.eclipse.org/projects/technology.dataspaceconnector
5 https://projects.eclipse.org/projects/technology.edc
[6] https://catena-x.net/en/angebote/edc-die-zentrale-komponente-fuer-die
[7] https://gitlab.cc-asp.fraunhofer.de/muejen/edc-aas-extension

The following sub-/components were changed or removed in/from the architecture:

- Input Handler was renamed to Serialization;
- Data Handler was renamed to Factory-Request;
- Sorter was renamed to Sorting;
- SmartResponse was removed.

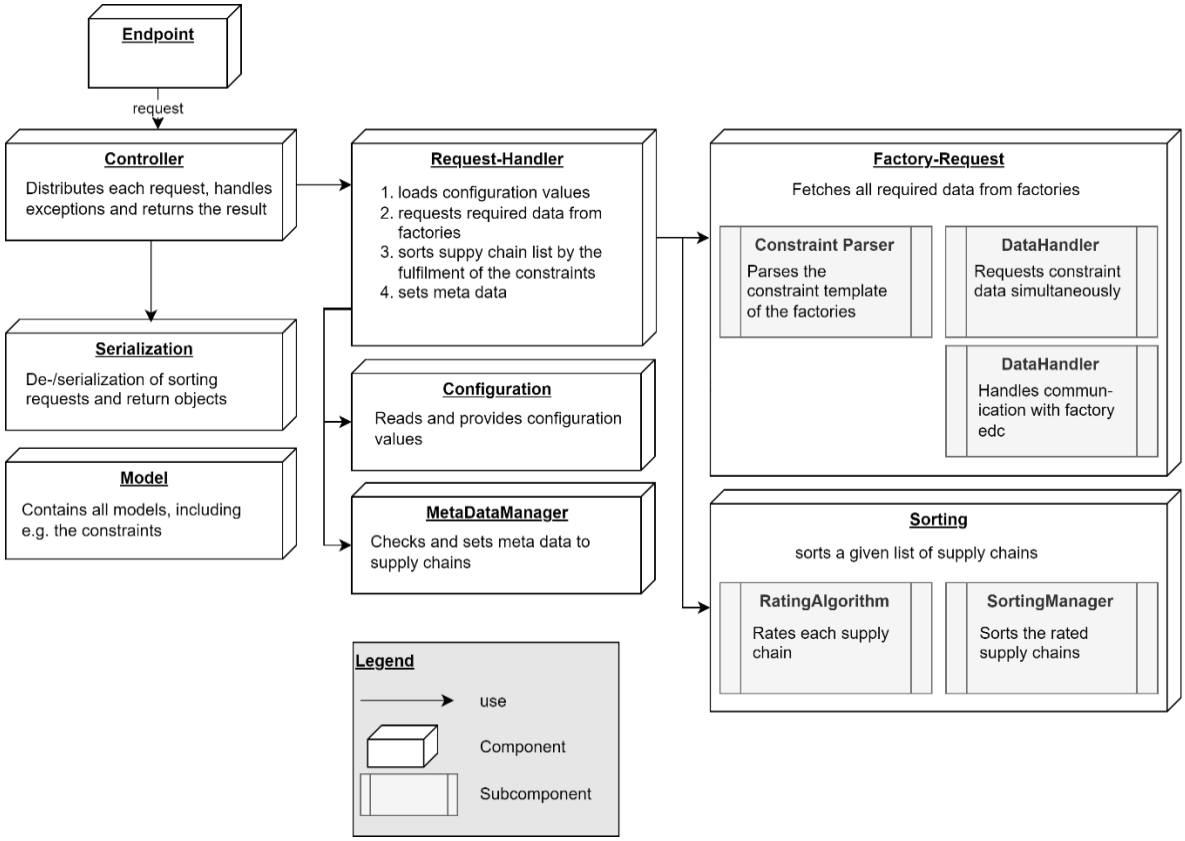

Figure 73 - SMMA Architecture

4.2.3 Implementation of SMMA

The following sections describe details of the implemented components and subcomponents. Components that were already described in D4.3 and without changes are skipped.

4.2.3.1 Constraints

The concrete constraints “Delivery Time”, “Price” and “Quantity” are implemented as default implementations. The corresponding classes inherit from an abstract class for the constraints, which allows an easy expansion with new constraints. A new constraint implementation needs to inherit from this abstract class and implement the required methods. Afterwards, the new constraint can be used.

In Figure 74, the data format of a constraint within a request to SMMA is shown as an example. There are three attributes of the constraint:

- value of the constraint

- type of the constraint e.g. “PRICE”, “DELIVERY_TIME” or “QUANTITY”
- weight: weighting factor of the constraint used to calculate the fulfilment of the constraints of a supply chain (see section 4.2.3.2).

Since a user may consider multiple constraints at the same time, the SMMA accepts an arbitrary number of constraints in the request.


```
[
  {
    "value": "20",
    "type": "PRICE",
    "weight": 1.0
  },
  {
    "value": "4000",
    "type": "QUANTITY",
    "weight": 1.5
  }
]
```


Figure 74 - Example Constraint

4.2.3.2 Rating Algorithm

Since the SMMA aims to sort the supply chains according to the fulfilment of the requested constraints, the fulfilment of a supply chain needs to be calculated. Therefore, the SMMA provides an interface called “RatingAlgorithm”, which calculates a rating value for a supply chain depending on the fulfilment of the concrete constraints. The supply chain list will be sorted based on the rated values.

However, an implementation of the rating algorithm is provided as a default implementation. The rate value is calculated based on the following formula:

r(s) = rate value of supply chain s
w_i = user defined weight of constraint i
d(i) = deviation of actual and target value of constraint i

$$r(s) = \sum_{i=0}^{n} w_i \, d(i)$$

The implementation of d(i) depends on the constraint. A higher value is better than a lower value. Possible implementations of d(i) could be:

x_i = actual value of constraint i of current supply chain
y_i = target value of constraint i of current supply chain

$$d(i) = \frac{x_i}{y_i} \text{ or } d(i) = \frac{y_i}{x_i}$$

Example calculation of a rate value of two supply chains

There are two supply chains to be evaluated based on the fulfilment of two constraints (a) Price with value 2 and (b) Quantity with value 4000. The constraint “Price” is more important and therefore has a weighting factor of 2, while the constraint “Quantity” has a weighting factor of 1.

Assumptions**:**

	Supply Chain 1 S_1	**Supply Chain 2 S_2**
Actual Price per piece	1€	2€
Actual possible Quantity	2000	4000

$r(S_1) = w_{price} * d(price) + w_{quantity} * d(quantity) = 2 * 2/1 + 1 * 2000/4000 = 4 + 0,5 = 4,5$

$r(S_2) = w_{price} * d(price) + w_{quantity} * d(quantity) = 2 * 2/2 + 1 * 4000/4000 = 2 + 1 = 3$

⇨ Supply chain S_1 has a better rating, since its rating value is higher than the rating value of S_2. However, S_1 does not fulfil the quantity constraint and therefore will be marked as a not fulfilling supply chain.

4.2.3.3 IDS Adapter

In previous versions of the SMMA, only the DSC was supported as an IDS connector. In the current version, an IDS adapter concept is introduced that provides the ability to use any standard-compliant IDS connector. Therefore, the SMMA provides an interface, which has to be implemented by each IDS adapter (see Figure 75).

As described in section 4.2.2, the EDC adapter class is the default implementation within the current version of the SMMA.

```
public interface IDSConnectorAdapter {

        /**
         * request aas content data from provider EDC
         *
         * @param connectorUrl URL to the provider EDC
         * @param idShortPath path to the requested aas element, starting at the desired
        submodel
         * @param contract predefined contract in JSON-String format
         * @return either the requested data or some error
         */

        public String getDataFromProvider(URL connectorUrl, List<String> idShortPath,
        String contract);

}
```

Figure 75 - IDS Adapter Interface

4.2.3.4 Configuration

Depending on the deployment of the SMMA, a user might want to redefine some configuration values like the running port of the application. Thus, the user can define specific configuration name-value pairs in a configuration file, which is parsed at start-up.

The following configuration values can be set:

- **Logging level** of the application
- **Port** of the HTTP-endpoint of the application
- **URL to the Eclipse Dataspace Connector** to which the SMMA belongs
- **File path to the EDC contract** to be used for contract negotiation with factory EDCs
- **Rating algorithm** to be used for evaluating the fulfilment of the supply chains
- **HTTP request** timeout used for waiting for a response from the factories until the connection attempt is aborted.

An example configuration can be seen in Figure 76.

```
# debugging
logging.level.root=INFO

# port
server.port=8080

# path to contract
contract.path=contractoffer.json

# consumer edc url
consumer-edc.url=http://consumer:8090

# rating algorithm
rating.algorithm=de.fraunhofer.iosb.ilt.smma.sorting.ratingalgorithm.DefaultRating

# http request timeout in sec
http-request.timeout=5
```

Figure 76 - Example Configuration

4.2.3.5 Updated Request

The SMMA is designed as an open service, which can be used by arbitrary platforms or clients. Since the SMMA requires some information, the client has to provide this information in the request. Besides the constraints, the SMMA needs following data:

- List of supply chains containing a list of factories
- Address of the factory IDS connector, which can be used to request the sensitive data
- Product Internationalized Resource Identifier (IRI) of the requested product.

This results in a minimal required structure of the request to the SMMA shown in Figure 77.

```
{
  "Constraints": [
    {
      "value": "20",
      "type": "PRICE",
      "weight": 1.0
    }
  ],
  "SupplyChains": [
    {
      "Factories": [
        {
          "FactoryConnectorUrl": "http://localhost:8090",
          "ProductIRI": "https://www.iosb.fraunhofer.de/aas/products/differential",
          …
        }
      ]
          …
  ]
}
```

Figure 77 - Minimal Structure of a request to SMMA

However, there is no standard for describing supply chains. That is why each client or platform most likely has its own structure for a supply chain. To avoid compatibility issues, the SMMA accepts besides the required attributes additional attributes. These additional attributes are stored while the request is being processed. After the process is completed, the additional attributes are added to the result set again.

4.2.4 AAS Sub-model Template for Constraints

Since the SMMA requests sensitive data from the factories to sort the supply chains, the SMMA needs to be able to analyse the data from the factories. That is why the factories need to provide their sensitive data in a known format. The Asset Administration Shell (AAS) is a reference implementation of the Platform Industry 4.0 for Digital Twins and well known in the industry 4.0 context.[8]

[8] https://www.plattform-i40.de/IP/Redaktion/DE/Downloads/Publikation/Details_of_the_Asset_Administration_Shell_Part1_V3.html

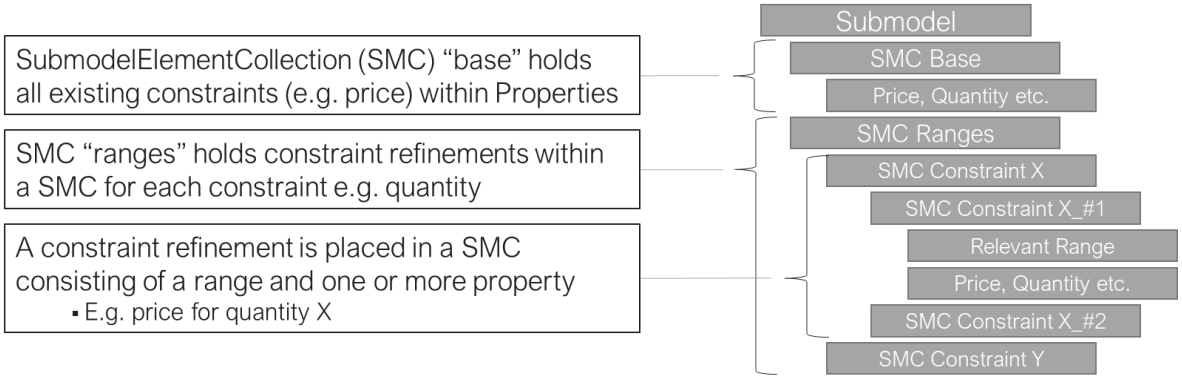

Figure 78 - AAS Template for constraint provision

Thus, the provision of sensitive data through an IDS connector via an AAS model ensures broad acceptance. However, in order for the SMMA to interpret the data, a semantically clear model for the factory is required. Therefore, an AAS sub-model template was proposed that can be easily integrated into existing AAS models on the factory side.

In Figure 78, the basic structure of the AAS template is shown. Below the Sub-model for the associated product are two Sub-model Element Collections (SMC):

a) base: The SMC with the name “base” contains a property for each constraint. The value of the property is the “base value”, which is used as fall-back value when no refinements in the “ranges” SMC match.
b) ranges: The SMC with the name “ranges” can contain several SMCs, which refine the values of the “base” SMC. Such a SMC is called an associated constraint e.g. “quantity”. This SMC in turn also has several SMCs named as the constraint name, the constant “range” and a consecutive number e.g. “quantity_range_1”. The lowest level of the SMC contains the concrete refinements in form of a Sub-model-Element of type Range, which defines to which range this refinement is applicable. It also contains Sub-model-Elements of type Property with the name of the constraint to which the refinement belongs.

Example Factory Constraint

To have a deeper look into the AAS constraint template, we introduce a brief example shown in Figure 79.

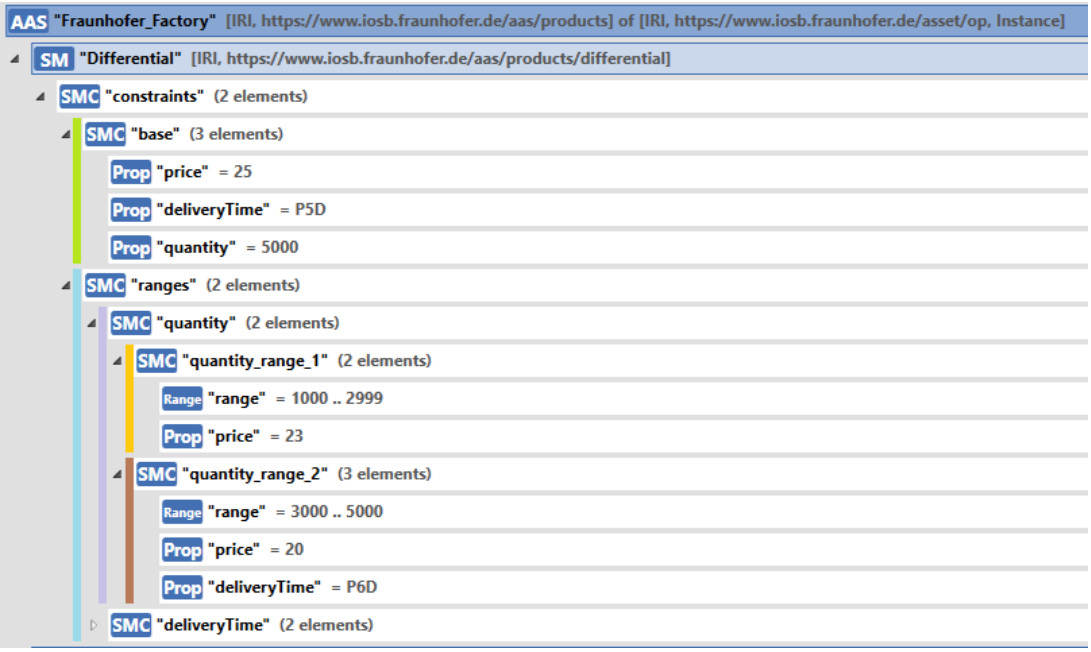

Figure 79 - Example of an AAS Factory Constraint

The example represents a factory *Fraunhofer_Factory* modelled as an AAS, which contains a Submodel for a product with name *Differential*. Technical details for the product are not shown for space reasons. All information regarding the constraints is bundled in a SMC named *constraints*. In this SMC there are two SMCs A) *base* and B) *ranges*. A) provides the base values for the constraints *price*, *deliveryTime* and *quantity* modelled as Properties. B) contains a set of refinements for the constraints *quantity* and *deliveryTime*, both modelled as SMCs.

In these SMCs there are the actual range-relation SMCs e.g. in the SMC *quantity* the SMC *quantity_range_1* and the SMC *quantity_range_2*. These SMCs contain exactly one Range element that defines in which range the base constraints will be overwritten. Which constraints will be overwritten depends on the properties inside the SMC. For example, in the SMC *quantity_range_1* only the price constraint will be overwritten with value 23 for a quantity between 1000 and 2999.

Let us have a look at a concrete request. Let us assume that a user requests 1500 pieces of the product *Differential*. Then the price base value will be overwritten by 23 per piece. Since there are no further refinements, the request of 1500 pieces can be answered with the constraints:

- Price: 23 per piece
- Delivery Time: 5 Days.

4.2.5 AAS Submodel Template for Constraints – Configuration Service

Since manually filling out the AAS sub-model template for constraints is very time-consuming and error-prone, a configuration service with a simple graphical editor was developed to guide the user through the process of instantiating the AAS constraint sub-model template.

The configuration service guides the user through the template process based on a user-friendly graphical user interface (GUI). The user starts by selecting a constraint to add (see Figure 80). Then she/he fills out the base values and the different ranges. At the end of the process, the user gets a summary of his input. During the process, the service keeps giving the explanations and useful hints to the user.

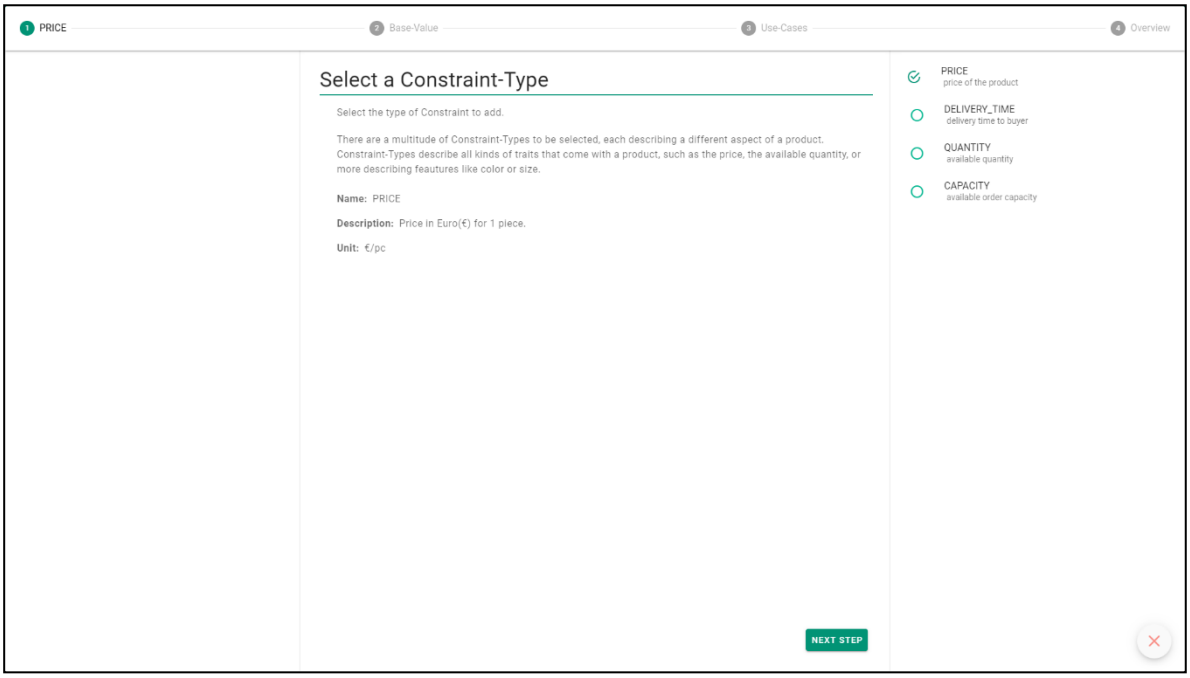

Figure 80 - Start page of the GUI for instantiation the sub-model template for constraints

Beside instantiating empty templates, the service also allows uploading already instantiated templates. This allows a user to easily edit existing configurations. To give the user a complete overview of his configuration, the service visualizes the values in a user-friendly way (see Figure 81). Once the user has completed his constraint configuration, the instantiated sub-model template can be downloaded and integrated into the target AAS model.

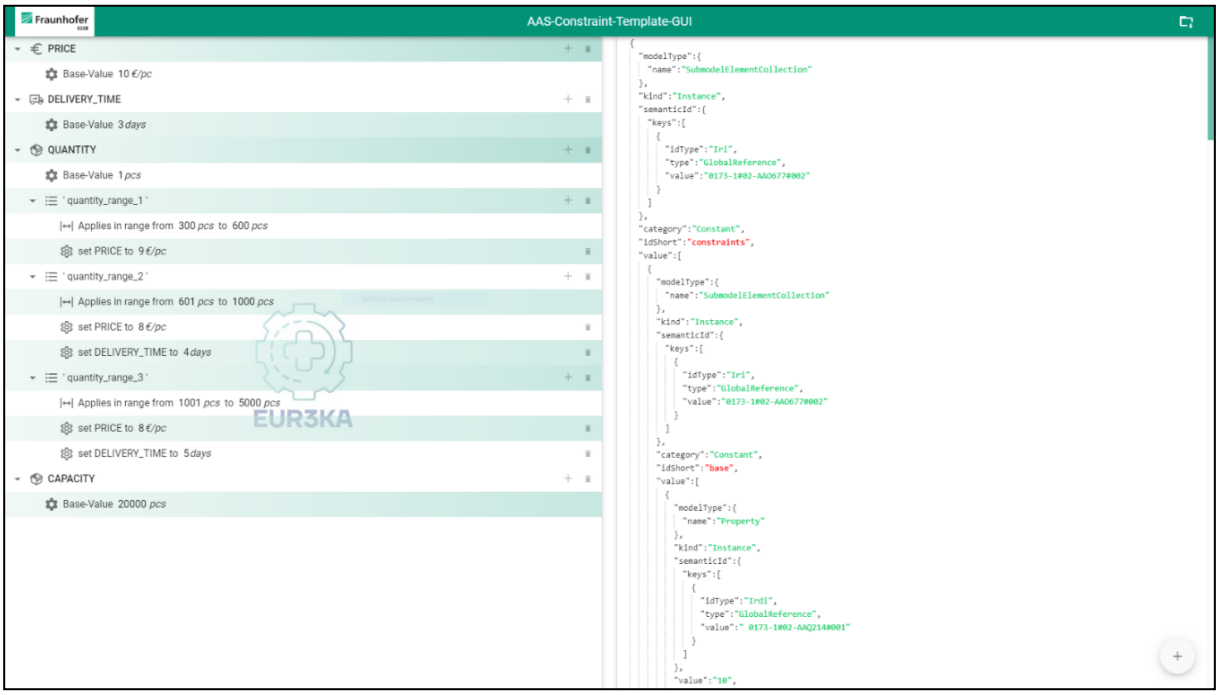

Figure 81 - Overview of the configured sub-model template for constraints

4.3 Production Quality Control Digital Workplace

Ensuring dimensional quality in production particularly with respect to 3D printed parts is of utmost necessity in an on-demand manufacturing network that processing, and analysis of current manufactured parts can be performed effectively. This implies both a design of a measurement plan with its execution and a secure place to store the information collected which can also be shared with other implied users.

This place is a digital workplace called M3Workspace platform. This is part of the metrological high-performance software developed by Innovalia, M3. M3 Workspace is a Platform As A Service (PAAS) cloud-based solution providing metrological after-sales assistance services. While traditional platforms allowed one to many (broadcast) type communications to deal with more general collaborative functions, Eur3ka has implemented the functionalities that demand a Peer 2 Peer (P2P) approach in such collaboration and that are fundamental to the delivery of a more customised QC (Quality Control) digital service. In order to implement such Data Spaces some improvements have been developed regarding the data exchanges. The Quality Information Framework 3.0 ISO23952 has been adopted to ensure seamless data exchange.

Compared to what was explained in deliverable D4.3, one of the biggest changes is the incorporation in M3Workspace of guides and training for the use of both the platform itself and the software. As M3 Workspace is a tool that will be available for use in the Eur3ka marketplace, it is vital that future users will be able to handle it easily.

Through M3 Workspace, it is possible to carry out the following activities:

- **Upload/download of documents**, mainly concerning to products design, measurement projects, measured parts or even metrological and statistical reports, supporting any format with which you work and depending on the type of file (CAD,

STEP, XML, CSV, txt…), This process can be both done by the customer and by Innovalia.

- Direct **upload of measurements results** from M3 software interface.
- **Licenses** management for M3 user/customer

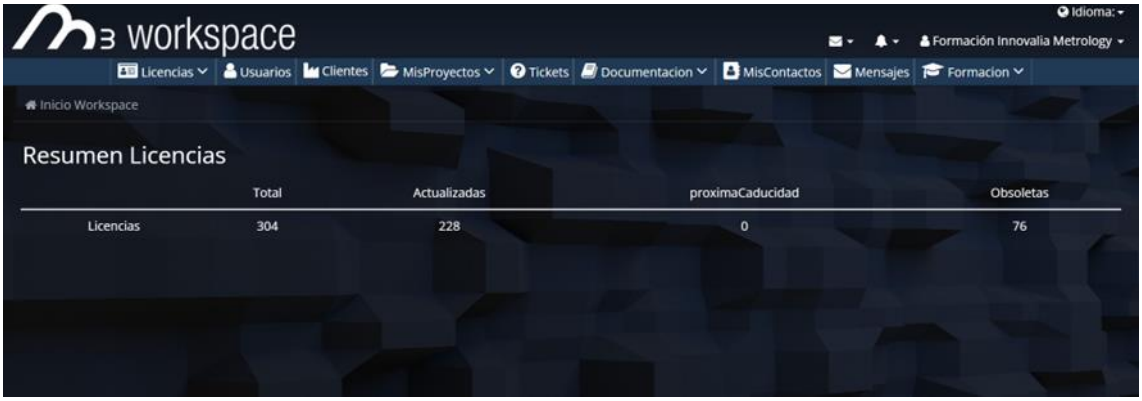

Figure 82 - Visualization of the license overview

- **Visualization of files on the proper M3 Workspace interface**, either CAD files, point clouds or metrological reports.
- **M3 training support and guidelines for users** (Webinars, tutorials...)

Figure 83 - Visualization of M3 Webinars offer page

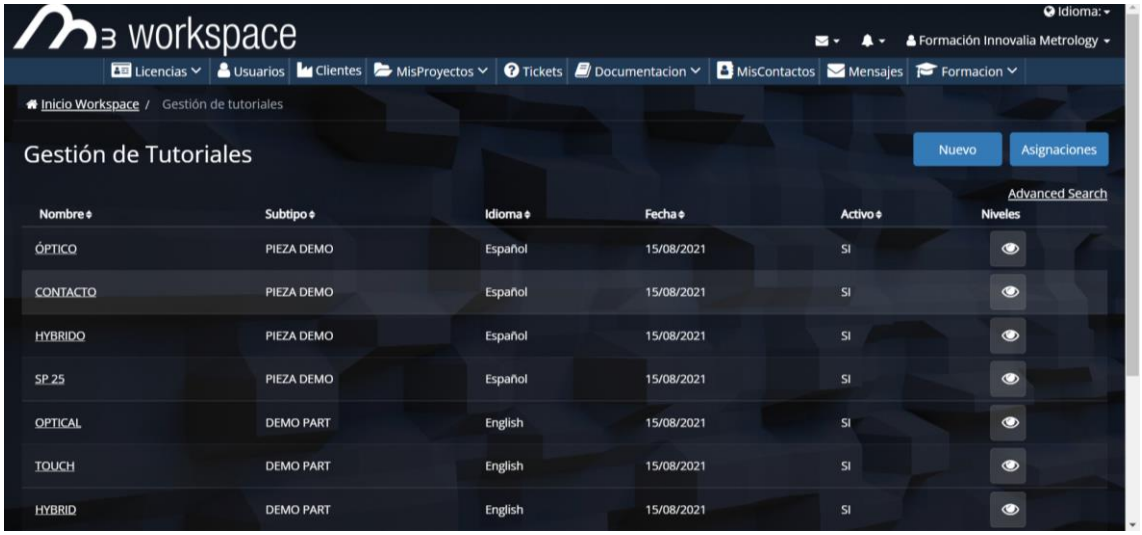

Figure 84 - Visualization of M3 tutorials offer page

Figure 85 - Visualization of M3 tutorial example

- **Management** of **support and guidelines** in M3

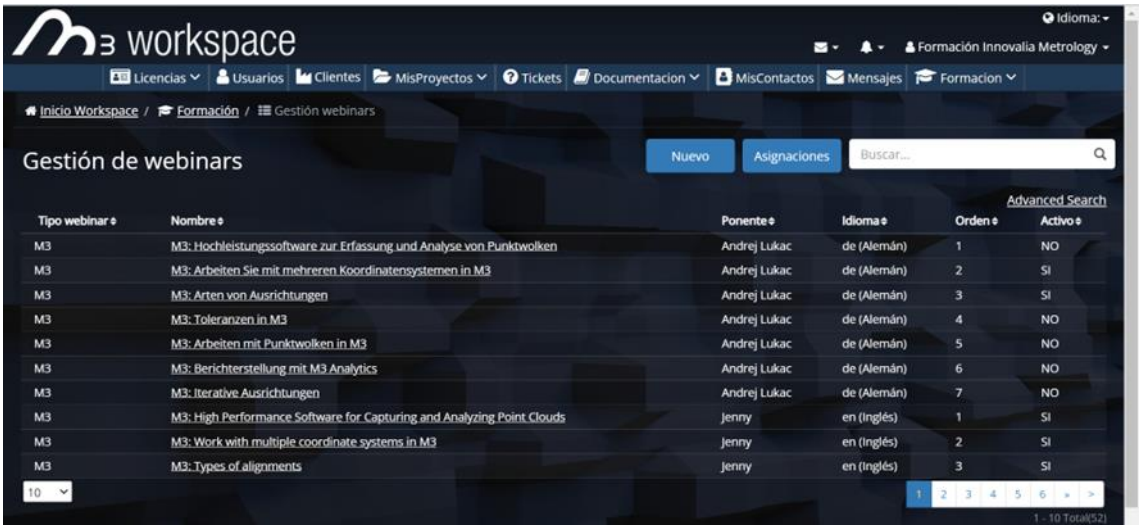

Figure 86 - Visualization of M3 webinar management (1)

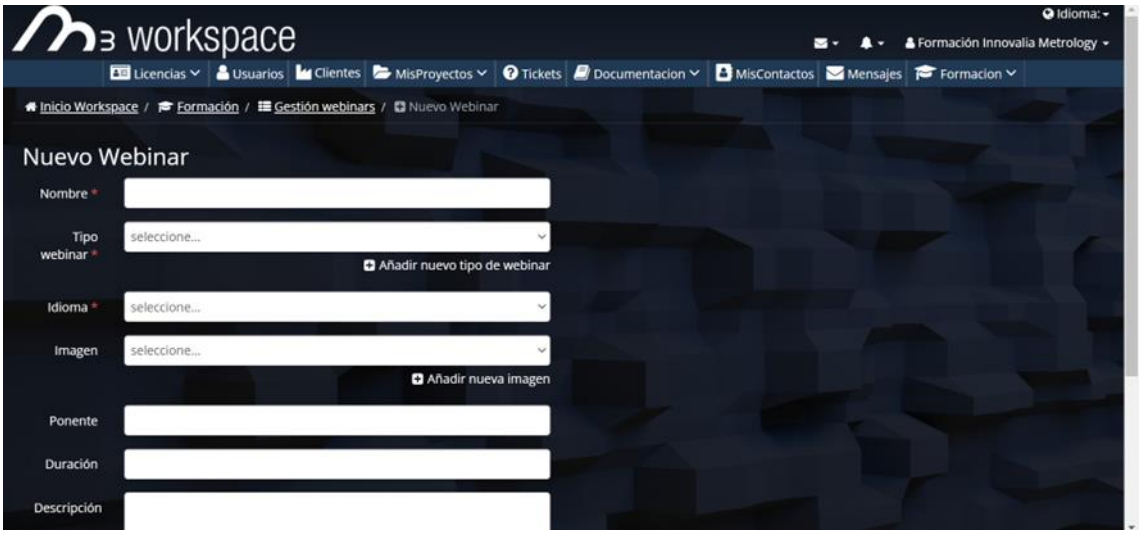

Figure 87 - Visualization of M3 management (2)

Context-Awareness Dashboard

The Context-Awareness Dashboard implemented by Engineering is based on Knowage, an open-source suite combining traditional data and big data sources into valuable and meaningful information. Knowage allows end-users to autonomously use the advanced self-service capabilities, in this way it is possible to build their own analysis, get insights on data, and turn them into actionable knowledge for effective decision-making processes. It includes a series of graphic tools to represent the data, their meaning allowing adaptive management of the contents within the analytical documents represented by the cockpits. The Cockpits is an intuitive interactive interface that can create, in a few clicks using drag and drop, a series of components like widgets and charts to graphically represent the data. Knowage is placed on the market as the open-source suite for business analytics, it is guaranteed the freedom to access the source code and collaborate in an international community thanks to industry-leading collaborations, while letting the users build their business solution that ensures strategic decision-making and improved productivity. Thanks to the community, the

suite evolves to meet the latest analytical needs, even combining traditional data with any Big Data source, and providing the needed tools to make successful projects.

Figure 88 - Context Awareness Dashboard charts example

The solution is adopted in SEAC pilot, where thanks to the open-source nature of the component, there was the chance to create an architecture designed as in Figure 89.

Figure 89 - Context Awareness Dashboard architecture

The functionalities of the Context Awareness Dashboard are extended to perform historical analysis, receive data using a secure endpoint to receive batch data in JSON format (Eur3ka System Adaptation), collect data plant in a MySQL DBMS, and at the end of the process there is the possibility to run processing on the datasets in order to apply logic and AI on them.

4.4 Repurposed Production Line Virtual Commissioning

During the COVID-19 pandemic, several challenges arose when repurposing existing production lines to manufacture products required for the pandemic situation. In addition to the fast response to produce the highly demanded products, these should be made according to design specifications, keeping the necessary manufacturing processes, and maintaining high-quality standards, particularly important when medical goods and pharmaceutical products are produced.

When repurposing existing production lines, the previously mentioned requirements bring additional challenges as the existing lines were not initially designed for the target that will be served after repurposing, is when the utilization of 3D Simulation and virtual commissioning technologies supports the repurposing, accelerating it and ensuring the validity of the line designed. (Figure 90)

Figure 90 - Detail of the product lifecycle of a production system and the repurposing phase

During the COVID-19 pandemic, the utilization of 3D Simulation and virtual commissioning technologies, included in Visual Components 4.0, accelerated the repurposing of existing production lines for producing new products, such as face shields, to protect medical personnel. While the first products manufactured were 3D printed, repurposing fully automated cells with injection moulding machines and robotic systems accelerated production and increased productivity. The virtual space provided by Visual Components 4.0 allowed collaboration between operators, designers, and automation experts situated in remote locations in a secure space to re-organize production and accelerate the commissioning and ramp-up of the highly demanded goods.

The biggest challenge when using 3D Simulation during the first moments of the COVID-19 pandemic was the availability of the digital models of the existing production lines where the products need to be manufactured. Despite the existence of CAD models, only the latest production lines had virtual models suitable for the fast creation of virtual simulation models and accelerate repurposing and commissioning. To overcome this limitation, simulation libraries developed within the EU project BOOST 4.0 were extended to accelerate the creation of virtual simulation models from the existing CAD and speed up the creation of the production line in the virtual space. Virtual models that combined with the communication technologies available within Visual Components 4.0 enabled the digital twin, which together with the virtual commissioning technologies validated the new production capabilities and deployed to the real system to start the production of the new products.

The VR training environment developed during Factory2Fit EU project, was the base for the development of the communication between all the stakeholders involved in the repurposing accelerating development, and commissioning setting up the equipment and training the operators while maintaining the social distancing and reaching production objectives fast and efficiently.

The pandemic has accelerated the development and integration in production environments of the digital technologies developed in several EU projects. It has also opened new research and development lines that have been addressed into Eur3ka, such as de digital continuity and how should be addressed to accelerate the commissioning of production lines for pandemic situations.

As mentioned, despite the existence of digital datasets, such as CAD data and production data, it is still required further integration into the digital continuity, which has been further developed in Eur3ka to integrate into the Cognitive Digital Twin (CDT). With the developments achieved so far within Eur3ka, the users have access to the process of creating the new production simulation through an intuitive user interface (UI) (Figure 91) that will allow to define the product to be manufactured based on the product taxonomy of assemblies and sub-assemblies. The processes to create the product based on tasks and available resources (equipment and personnel) and the production flow.

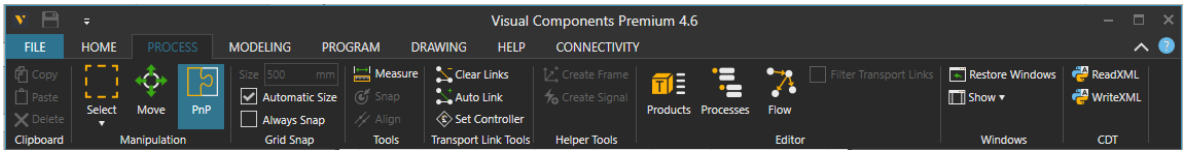

Figure 91 - Screenshot of the user interface provided by Visual Components 4.0 to create the 3D simulation or the new production scenario

Under Eur3ka has been created the data interfaces to ensure digital continuity from concept to operation, maintaining the data consistency and the semantics along the entire process, extending the data sets while the product lifecycle is evolving, the user will be able to save all the data sets in XML and retrieve existing ones (Figure 91) datasets that can be reused and extended along the entire lifecycle of the production line.

To facilitate the creation of the simulation models a generic simulation library based on process modelling, which can be tailored for a wide number or user requirements, has been developed into Visual Components 4.0 allowing the user to create the initial 3D simulation models. (Figure 92)

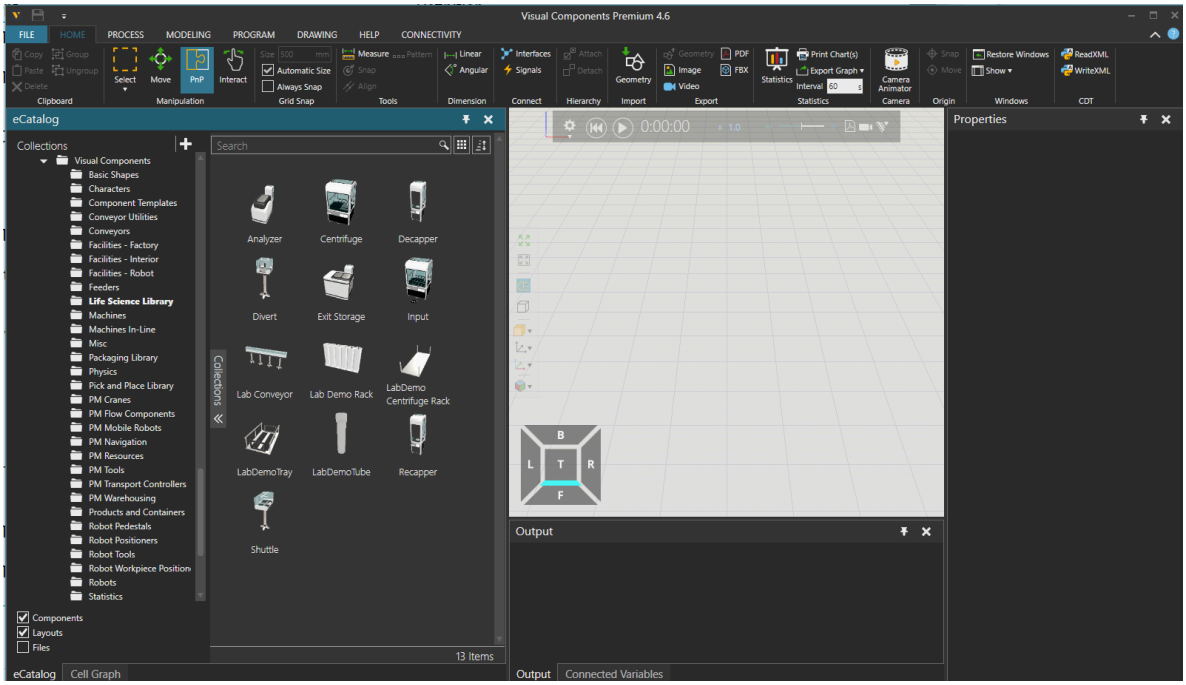

Figure 92 - Screenshot of the library developed targeting medical and life sciences purposes

Once the production line has been configured, using the available resources, and the production has been validated can be initiated the virtual commissioning phase. During this phase the virtual scenario is connected to automation controllers, virtual or real to test and validate the behaviours, of the virtual models against the control programs (Figure 93). The user can map into the UI the signals between the controller and the virtual system as indicated in Figure 93. Once the signals have been mapped the verification and validation process can be initiated in the virtual space, identifying errors, and correcting them even before the real system has started to be deployed. This saves time and avoids costly mistakes, accelerating the commissioning and ramp up.

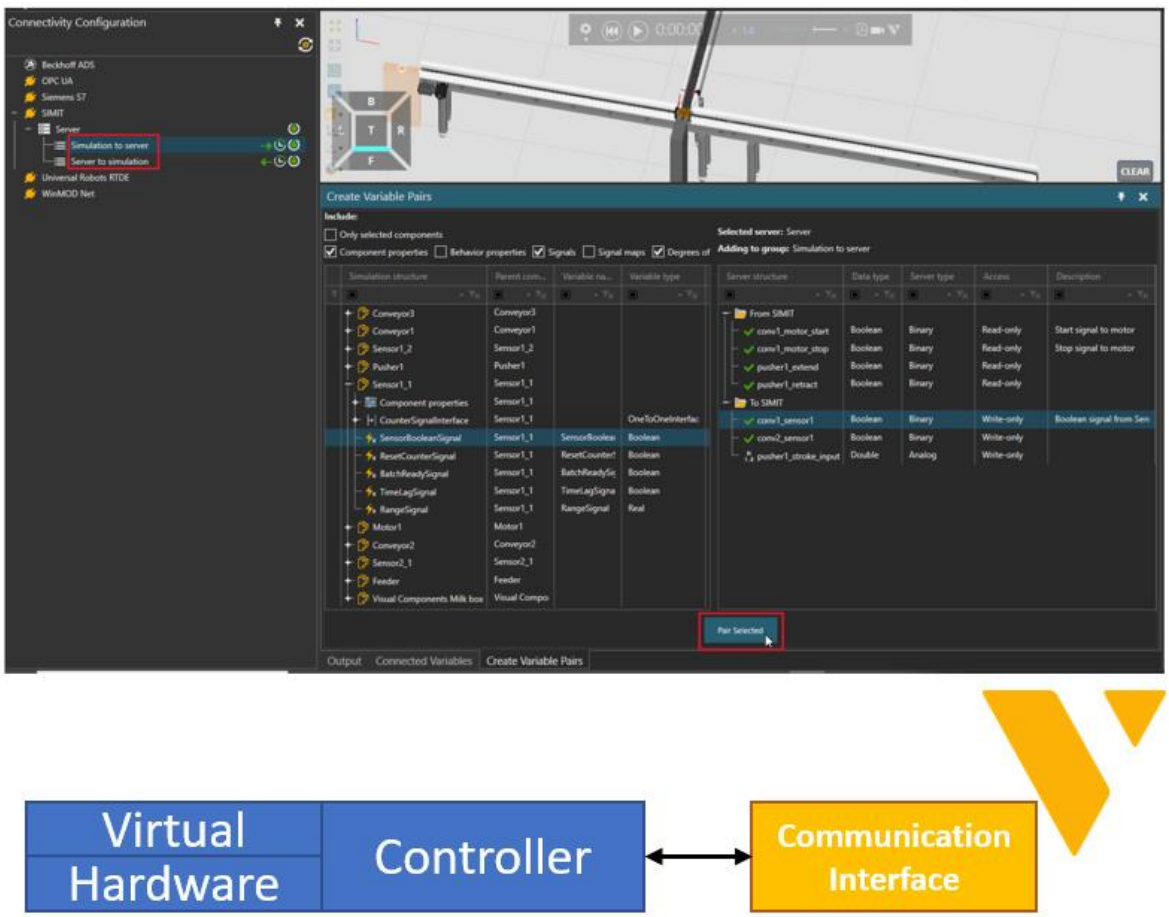

Figure 93 - Screenshot of the communication interface and the connectivity feature to verify and validate the control into the virtual environment before commissioning

As a result, the digital continuity enabled by the CDT, facilitates the communication between the different stakeholders, sharing the same information datasets, through the different tools, along the entire lifecycle. It also ensures that the production line can be easily reconfigured for new products, upgrading for new production requirements even decommissioning and reuse of the resources for new production lines.

Currently the work is progressing within the SVM pilot, extending the data sets and creating the configuration tool for the concept the manufacturing line.

4.5 Quality Control Design Tools

In a crisis situation where products are in short supply, it is vital to reduce the waste of products that do not pass quality control. Moreover, with the focus on medical products, quality plays a key role. In particular, one of Eur3ka's objectives is to achieve Digital Lean Zero Defect Manufacturing (ZDM).

To ensure quality of products and services, Eur3ka will follow a Quality Management System (QMS), in line with what is explained in deliverable D4.3. However, the concrete tool that will support Eur3ka to manage quality control from the 3D manufactured parts is a metrology software called M3. This is the metrological high-performance software developed by Innovalia. Specifically, it is a high-performance software for online automatic scanning point

cloud capture and analysis for the reliable and efficient acquisition of 3D information for different materials.

Quality control can be carried out in the following ways: off-line, with the finished product and in a measuring room; by-line, next to the production line; or in-line, integrated into the production line itself. M3 software allows not online to analyse information from a machine from Innovalia but also to analyse information from other machines located thus by-line or in-line.

In relation to the machines that collect metrology information, the way they measure is usually of two types: direct mechanical contact (tactile probe or stylus) or non-contact optical system (laser scanning probe and interferometers). In particular, the optical scanner is being used more and more for the scanning of complex parts because it avoids the need for a measurement programme on the machine that requires a lot of detail. When using tactile sensors, if there is no good plan or if there are surfaces with holes, an unwanted collision can occur and the program will stop, causing problems and delays. In addition, parts made from plastics are often susceptible to deformation from touch sensors.

During the Eur3ka project, new functionalities of the M3 platform have been developed in order to improve the performances of the metrology and quality control process.

One of the improvements is the adaptation to the QIF 3.0 unified XML framework standard for computer quality measurement systems Not only in the exchange of data with other users, which has been discussed in depth with the M3 Workspace, but also in the exchange of data for the processes themselves within M3 software.

Geometric Dimensioning and Tolerancing (GD&T) is a system for defining engineering tolerances. Due to imperfections in manufacturing and inspection processes, it is necessary to define tolerances for dimensions (lengths, diameters, radii, etc.) and geometries (parallelism, perpendicularity, eccentricity, etc.), as the manufactured part will never exactly match the design model. The digital quality control thread starts with the virtualisation of the manufactured part by high-density optical scanning and produces a high-precision point cloud. In addition, CAD (STEP) is enhanced by adding semantic GD&T (Geometrical Dimensioning and Tolerancing) data. With this information, the measurement plan is automatically generated. Based on GD&T, Datapixel's virtual metrology module automatically analyses the point cloud. The digital metrology thread is interoperable thanks to the integration of metrology standards, in particular QIF (Quality Information Framework). Metrology results are then also available for closed-loop process optimisation.

Figure 94 - Quality Information Framework

The number of points in the point cloud is very important for the metrology process, however, a large number of points implies a large amount of data. Vectors have been introduced to reduce the amount of data used. These vectors are also crucial when using algorithms to perform automatic feature extractions.

The point clouds need to be compared with nominal values (usually the original design, CAD); however, the coordinates of the original CAD and the point cloud do not match, therefore an alignment has to be performed. The main challenge in CAD-based coordinate metrology is the alignment of the coordinate system of the data captured from the physical part during measurement and the reference coordinate of the CAD model. There are two principal solutions that carry out alignments.

- Physical alignment: The part is moved using a customized mechanical fixture until the reference elements are in the right place. This is expensive and only viable for the measurement of large series in serial production.
- Mathematical alignment: The part is not moved rather the coordinate system of metrology data which is aligned mathematically.

To perform the alignment M3 has several methods available (mathematically). A specific improvement has been made during Eur3ka regarding the Reference Point System alignment. The technique facilitates the extraction of the same geometries in both the scanned point cloud and the CAD model. The geometries are then paired, and assigned a positional constraint, directional constraint and weight for each reference. This method simulates the alignment that would have been obtained by using tailored mechanical fixtures to position the part and leads to an optimal metrology accuracy. The result of the RPS is a roto-translation matrix that can then be applied to the acquired point cloud coordinate system.

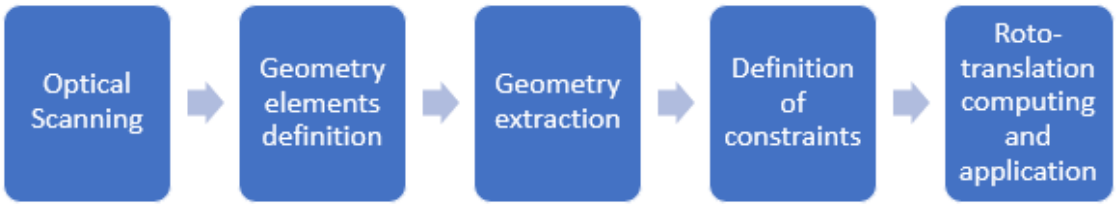

Figure 95 - Steps of the RPS alignment

1. Optical scanning of the part which creates a 3D point cloud.
2. Definition of the geometry elements that are going to be used as the reference for the alignment.
3. Automatic extraction of the geometric information both from the CAD model and the point cloud. The extracted elements are defined by the positional and orientation characteristics.
4. Once the geometries are extracted, the software defines the constrains that should be applied to the positions and orientations.
5. Finally, the software computes the roto-translation matrix needed to perform the coordinate system homogenization.

An important step of the developed alignment process is the automatic extraction of the geometries from the point cloud. For the development of the extraction module, Datapixel has used its Geometric Feature Extraction (GFX) library. The improvements concern both the positions of the points in the point cloud used in the extraction and the vectors of these points as inputs. For each scanned point, the vector of the supporting surface can be evaluated by the orientation of the scanner. These vectors are recorded as point cloud data and then used for a second, improved extraction.

The algorithm follows these steps:

1. ROI segmentation. Initially the ROI or Region of interest needed to be selected by the user. With the new improvements the segmentation is automatic.
2. Filtering. The main objective here is the removal of noise and other undesirable effects on the results.
3. Best fitting (Gauss-Newton). This step is crucial. The improvements have been to find algorithms that by means of linear and non-linear techniques can find an ideal geometric entity (regular surface) capable of minimising the sum of the squared deviations between that geometric entity and the scanned points.

Another aspect improved within M3 during Eur3ka is the disparity map, which allows visualising the differences between the CAD model and the best-fitted geometric entity which is an almost exact reproduction of the manufactured part. Specifically, a disparity map is a tool that, through a coloured 3D graphic, shows the deviation in each region of the part. Different colours reflect a different level of deviation with red demonstrating an excess of material and blue a lack of material. The disparity map is helpful for quality control throughout the manufacturing process and for providing information that can optimize the design process. Regarding quality control, one of the principal uses of the disparity map is the identification of deformations produced by the manufacturing process which can then be rectified by modifying process parameters or the part design. The map comes in the form of a 3D representation of the local deviations of the surfaces with each surface area given an annotation.

Initially the disparity map was based on a triangular mesh which was not so intuitive or readable.

The disparity map is particularly useful for evaluating the excess or lack of material of the manufacturing process in hybrid AM (Additive Manufacturing) / SM (Subtractive Manufacturing process). Lack of material can be corrected by adding material using AM, and excess material can be corrected by SM machining.

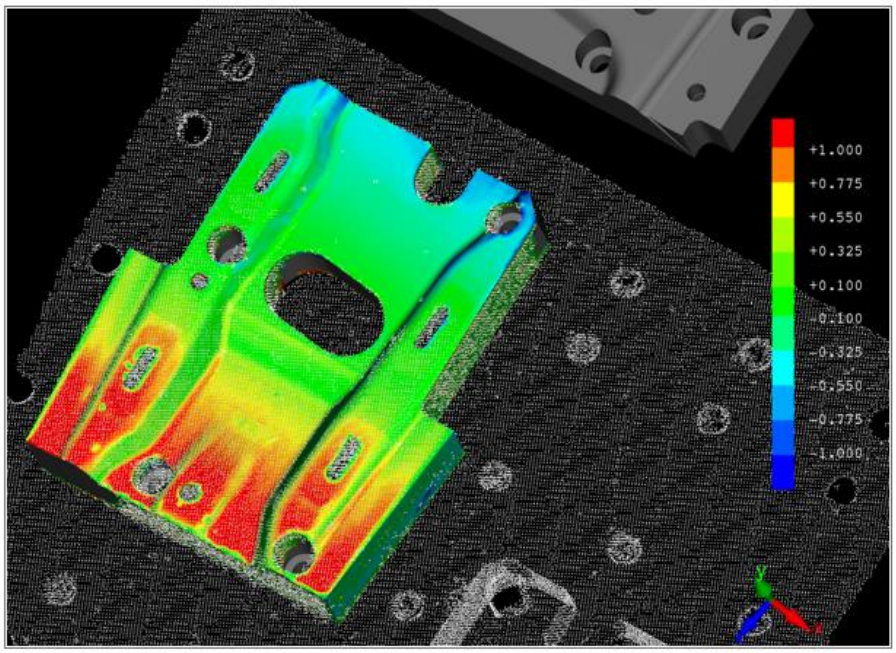

Figure 96 - Example of the disparity map of a manufactured part, tolerances are defined at +/- 1mm

5 Conclusions

In line with the Eur3ka strategy, this document presents the tools and services that have been developed in the course of Eur3ka. The P&R now has everything necessary to meet the objectives set during the project. It has IT tools that will be accessible on the DFA's ZX Marketplace so that companies can react appropriately in a crisis, and it has services that enable the deployment of a rapid response network with validated products/designs and validated production capacity. The integration of all these tools and services is the next step in the Eur3ka project. The tools and services were simultaneously improved and developed thanks to the implementation of the pilots (WP5). Once the results are known and the relevant improvements and adaptations of the tools and services have been made, the validation process remains to be carried out so that they can be part of the P&R. For this purpose, use will be made of the established Certification framework, which in turn is supported by the Q-Med Tech platform.

As mentioned above, Eur3ka has tools and services that are key to one or more stages both before and during a health crisis. Furthermore, knowing the final status of the tools and services, the partnerships and collaborative frameworks under which the P&R will operate can be established, therefore is one of Eur3ka´s ongoing targets. The user journey of all users delimited in D5.2 will be characterised by mapping also the tools or services they could use within the P&R. In addition, the final P&R architecture will be characterised with reference to these tools and services.

As described in this document, all the services are grouped by pre-crisis assessment, pre-crisis preparation and crisis response, with a clear mapping to the Reference Architecture designed in D2.1 representing the main pillars of the 4 Grand Scenarios.

Particular attention was put on the cross-sectorial supply network, to ensure the resilience and the dynamic configuration of that based on the production capabilities, a smart search engine to match medical product manufacturing specifications and Eur3ka manufacturing network resources, a way to guarantee the production continuity respecting at the same time security needs and finally the services useful to obtain flexible manufacturing automation and products.

6 References

[1] Mizoguchi R, Ikeda M,Towards ontology engineering. Journal-Japanese Society for Artificial Intelligence 1998; 13:9-10

[2] Foehr M, Jäger T, Turrin C, et al., Implementation of a methodology for consideration of product quality within discrete manufacturing. IFAC Proceedings Volume 2013; 46(9):863-868.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016175