MDR compliant medical device production at the Point of Care

Munich 07.03.2024

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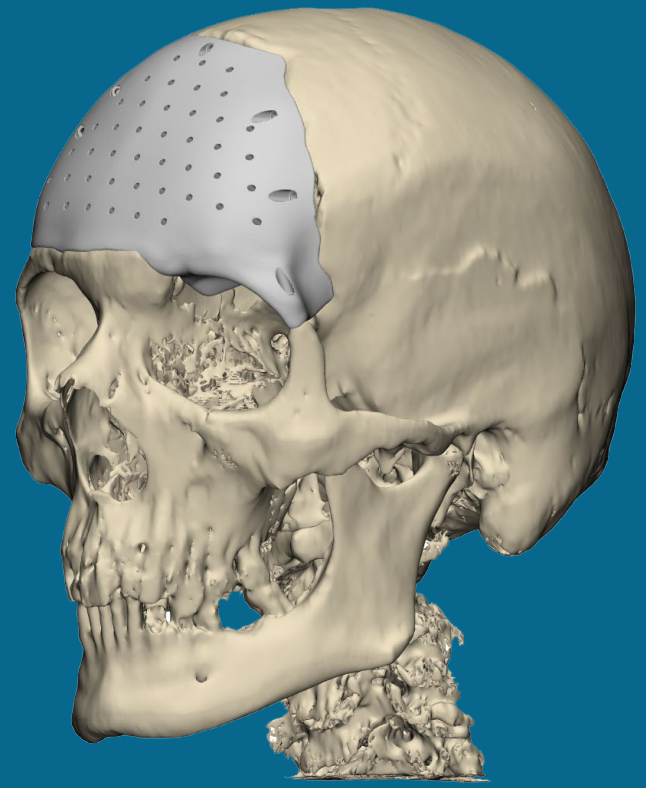
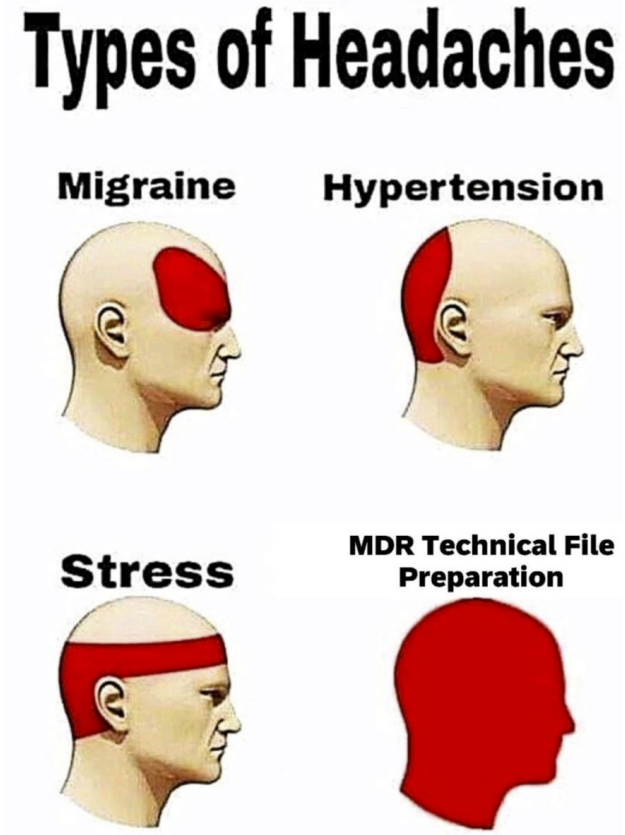
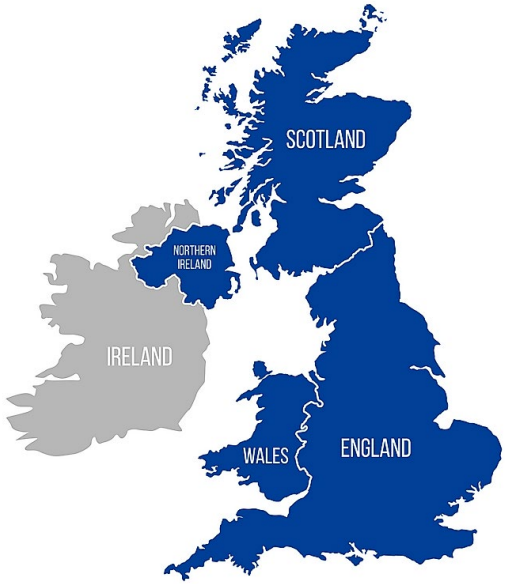


MDR 2017/745 – Medical Device Regulation

+Switzerland, Norway, Turkey, etc.





UK MDR 2002 + Guidelines

MDR 2017/745 Article 5 / 5

"With the exception of the relevant general safety and performance Requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:"

(European Commission, 2017)

MDR 2017/745 – Article 5/5 – Annex I Requirements

Requirements for Products

- Quality management system
- Product documentation according to general safety and performance requirements
- Post market surveillance

Products:

- Anatomical models
- Surgical guides
- Implants
- ……

Requirements for Equipment / Material / Personnel

- Process qualification / validation
- Process management (changes)
- Training
- Supplier Management
- Maintenance

Equipment / Material / Personnel:

- Surgical planning software
- 3D Printer
- Post processing tools
- QA instruments (e.g. 3D scanner)
- Operating personnel

Why should we care about MDR?

Ethics

MedTech industry quality standards

Legal

Liability;
Local Authorities audits

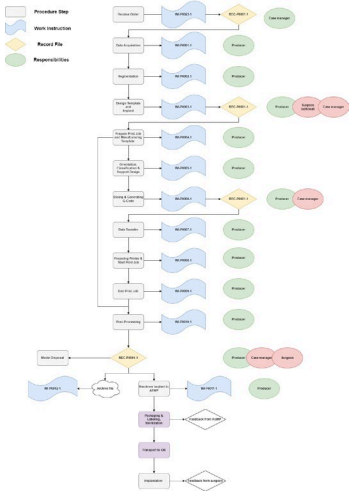
Policies

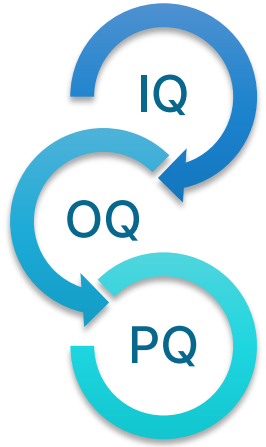
“No Product Sterilization without IFU”

Efforts to fulfill MDR Annex I

3D print lab operations

Legal compliance (MDR Article 5/5)





3 FTE over two years to build up

Our milestones

Road to First in Human 3D-printed PEEK Cranial Implant at POC:

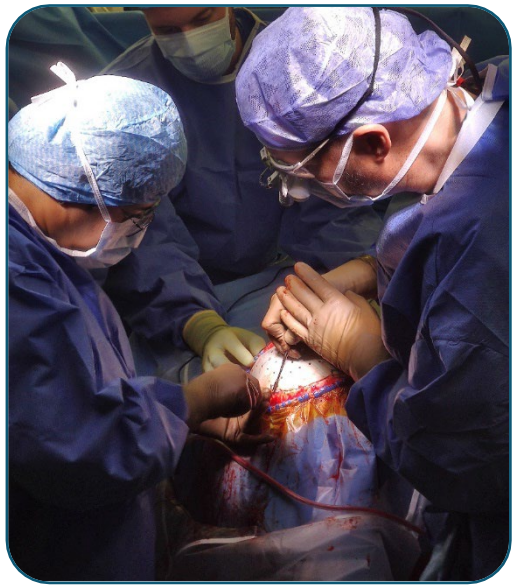
02 / 2023

- POC APP AG founded in Basel

07 / 2023

- QMS
- Production Process (PEEK Cranial Implant)

08 / 2023



University Hospital Basel

09 / 2023

SALK Salzburger Landeskliniken

Who are we?

Bernhard Pultar
CEO
MedTech QA/RA Expert

Dr. Neha Sharma
CMO
CMF Surgeon

Daniel Seiler
CTO
Med 3DP Expert

Prof. Florian Thieringer
Clinical Advisor
Chair CMF Surgery

Dr. Özlem Weiss
Regulatory Advisor
MedTech/3DP Expert

Ralf Schumacher
Strategic Advisor
MedTech/3DP Expert

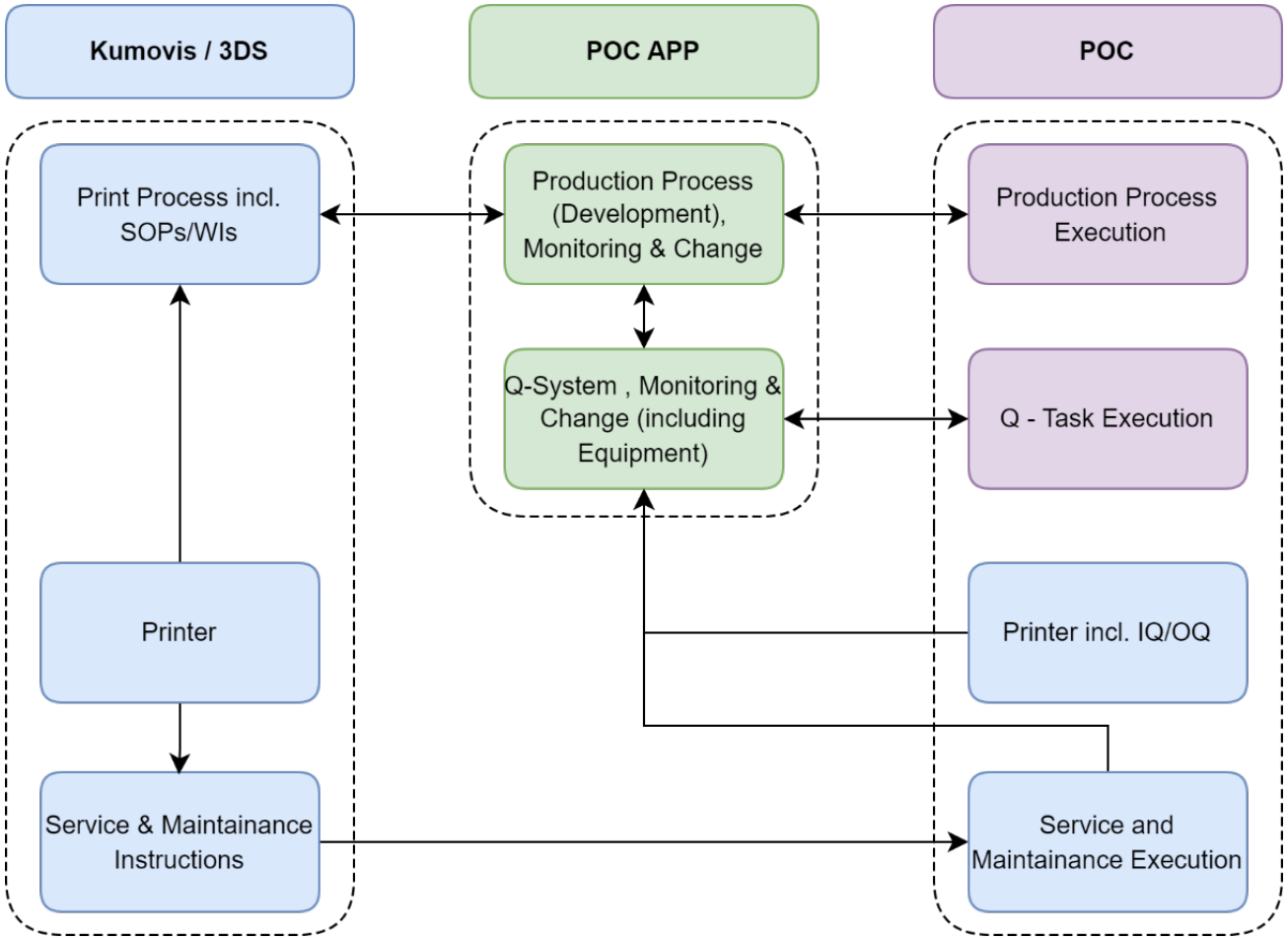
POC APP

What we do? – QM as a service for Point of Care*

- Building and running of **QMS** and **Quality Assurance**
- Performing of risk-based evidence **product documentation (Anat. Models, Surgical Guides, Implants)**
- Implementation of a register to **track clinical data** and performance
- Performance of **production process qualification**
- **Qualifying** of equipment / software supplier
- Implementation of **maintenance plan**
- **Training** of personnel

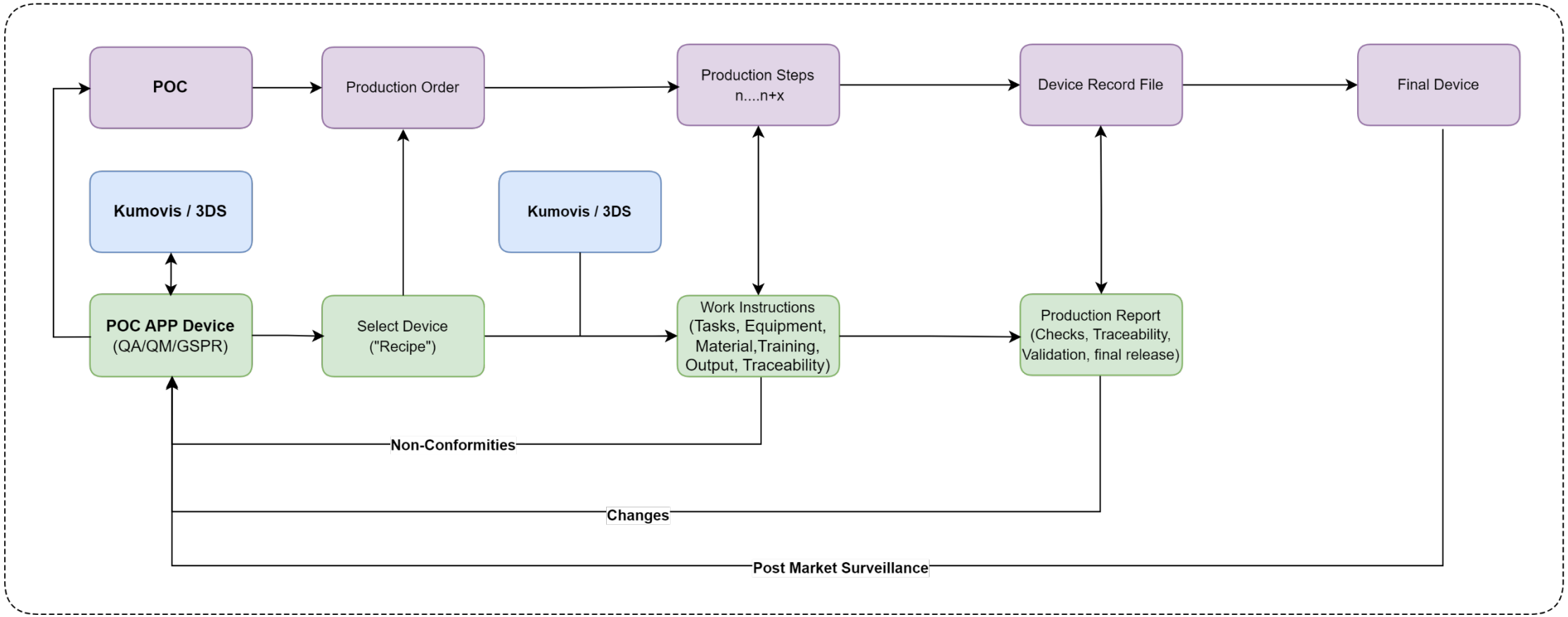
* In compliance with MDR 2017/745

Integration of manufacturing process and QM at POC



Example for QM as a Service for Point of Care

POC Production
(MDR 2017/745 , Article 5/5)



Benefits of Quality Management as a Service by POC APP

Quality assurance
Save and effective patient specific products

Quality improvement
Continuous quality management and improvement (POC APP network)

Legal compliance
Peace of Mind

Shared costs
Predictable and shared legal compliance costs

Collaboration

POC Assessment

- Clarification of needs (anatomical models, surgical guides, implants, indications,..)
- Definition of target solution
- i.e. one day workshop

POC APP Implementation

- Implementation of QMS
- Implementation of MDR compliant product processes
- i.e. one quarter

POC QA / RA Monitoring

- Change management / Non-conformities
- Regulatory and quality management updates
- Post market surveillance

Get in touch!

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