Medical Device Regulation Conformity Routes
The goal is to ensure a simple and easy to understand regulatory environment for medical devices, which ensures the efficient functioning of the internal market.
Conformity Assessment Procedure

1. Classification of the medical product
2. Quality management system
3. Technical documentation
4. CE marking

Follow-up
- Post market surveillance

Risk management
- General safety and performance requirements
- Clinical evaluation

Usability

Idea to market
INTENDED PATIENT POPULATION
The DEMOGRAPHICS of the patient

INTENDED USER
WHO should use the device

CLAIMS
WHAT the device does
- Prevention
- Diagnosis/Prognosis (Support)
- Management/Monitoring
- Treatment/Alleviation
- Predicate Device

INTENDED USE
HOW to use the device

INDICATIONS FOR USE
The CLINICAL PICTURE of the patient
Contraindications

PRINCIPLES OF OPERATION
HOW the device achieves its Intended Purpose
Annex VIII - Classification Rules

- Class I
- Class I s / m / r
- Class IIa
- Class IIb
- Class III

Annex I - General Safety and Performance Requirements
Annex II - Technical Documentation
Annex III - Documentation on Post Market Surveillance
Annex VI - UDI - Unique Device Identification
According to risk-based rules (e.g. EU) or lists (e.g. USA)
Intended use of the device

- Non-active medical device
- Active medical device
- Special rules

Invasive medical devices

- Type and duration of invasiveness

Non-Invasive medical devices
Long time
Invasive
Not active

Device + software
Not invasive
Short term

Not invasive
Radiation
Transient
QMS referred to in Article 10(9)
+
Preparation of the technical documentation according to Annex II + III

Annex IV
I
EU Declaration of Conformity
Manufacturer assigns
QMS referred to in Article 10(9) +
Preparation of the technical documentation according to Annex II + III

<table>
<thead>
<tr>
<th>Annex XI</th>
<th>IIa</th>
<th>Costs: 20k€</th>
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<tbody>
<tr>
<td>product conformity testing</td>
<td>IIa</td>
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<tr>
<td>Manufacturer assigns</td>
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<td>CE XXXX</td>
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</table>
QMS referred to in Article 10(9) +
Preparation of the technical documentation according to Annex II + III

Annex X
IIb + III
type examination

Annex XI
IIb + III
Costs: 20k€
product conformity testing

Manufacturer assigns
CE xxxx

Costs: 10k€ per Batch
QMS referred to in Article 10(9) +
Preparation of the technical documentation according to Annex II + III

Annex IX
I + IIa + IIb + III

CompleteQMS

Costs: 20k€
Each Scope: 15k€
Manufacturer assigns

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QMS referred to in Article 10(9) +
Preparation of the technical documentation according to Annex II + III

Annex IV

EU Declaration of Conformity
Manufacturer assigns

Annex X

Costs: 10k€ per Batch

IIa + IIb + III
Type examination

Product conformity testing
Manufacturer assigns

Annex IX

Complete QMS
Manufacturer assigns

Annex IX

Manufacturer assigns

IIa + IIb + III
Costs: 20k€

Each Scope: 15k€

IIa + IIb + III

Costs: 20k€

Manufacturer assigns

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QMS referred to in Article 10(9) +
Preparation of the technical documentation according to Annex II + III

Annex IV
II
EU Declaration of Conformity
Manufacturer assigns

Annex X
IIb + III
type examination

Annex IX
I + IIa + IIb + III
CompleteQMS
Manufacturer assigns

Costs: 10k€
per Batch

IIa + IIb + III
Costs: 20k€

product conformity testing

Costs: 30k€

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Medical Device Regulation Performing the Conformity Assessment
Roles

- Notified Body
- Authorities
- EU-Commission
- Manufacturer
- Supplier
- Importer
- Distributor
- Marketplace
- Representative

Critical Suppliers and outsourced services only
Declaration of conformity

ISO 13485
MDR Article 10.9

Risk Management Plan
Risk analysis
Formative Evaluation
Summative Evaluation

Use specification
User Requirements
Product Requirements
Clinical Evaluation Plan
MDR Article 10.9
Development - Test Plan SW and EMC
ISO 13485
Intended Purpose

Label
GSPR

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Step by step to QMS certification

1. Building awareness for quality management
2. Inventory and formulation of objectives
3. QM documentation
4. Staff training
5. Internal Audit
6. Management review
7. Certification
6. management of resources
- Human Resources

4. quality management system
- documentary requirements
- Technical documentation

5. management responsibility
- quality management manual

MDR-QMS
scheme
Thu
act
check

7. product realization
- Development
- Development changes
- Clinical life cycle
- Risk management
- software development
- Supplier management
- Identification and traceability
- External communication
- Production

8. measurement, analysis and improvement
- Improvement
- Corrective and preventive measures
- Complaints and feedback
- Vigilance
- analysis and management evaluation
- Quality audit
- Post-market monitoring
Timeline for the creation of a QMS

**Directives, laws and standards**
- EN ISO 13485
- MDR 2017/745

**QM specification documentation**
- lawsuits
- templates

**Quality records**
- Documents (changeable)
- records (not changeable)
- e.g. completed protocols, reports, plans
QMS setup

- **quality policy**
  - "soul" of the QMS
  - Q policy usually public ("corporate values")

- **process landscape**
  - New employees find their way around quickly
  - Consistent workflows

- **templates**
  - "Small consultant" for document creation
  - You don't always have to think of everything yourself

- **Quality records and documents**
  - Actual documentation
  - Required by the quality management system
Certificate

Stage 2 Audit

Stage 1 QMS

Technical File Assessment

Contact approvals

Preparation

Certification check and notified body internal assessment
MDR TD compilation
Compile the perfect file

Annex II

Annex III

GSPR

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MDR Common mistakes
DECLARATION OF INTEREST (CER)

VIGILANCE PROCEDURE

PMCF NOT DETAILED

RISK BENEFIT WITHOUT CER

LABELLING

STATE OF THE ART

BIOLOGICAL ASSESSMENTS
DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

• Basic UDI-DI or other unambiguous reference allowing traceability
• Intended population, indications, contraindications, warnings
• Principle of operation of the device and mode of action
• Rationale for considering the product a medical device
• Device classification, applicable rule and rationale
• Explanation of any novel features
DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

• Description of accessories
• Description of all variants of the device
• Description of the key functional elements
• Description of all the relevant raw materials
• Technical specifications, dimensions and performance attributes
• Reference and overview of previous and similar generations of the subject device and device market history
DESIGN AND MANUFACTURING INFORMATION

• Information about the design stages
• Complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing
• Identification of all sites including suppliers and subcontractors; where design and manufacturing activities are performed
Polymerization
Injection molding…

Material processing like cutting, cleaning, polishing, gluing

Additives like fillers, reinforcement, composites, UV, Blocker, flame retardants, pigments and dyes, stabilizers

Raw materials

Configuration

Historical data

Manufacturing

Sterilization, process condition

Lubricants, coating, glue, cleaning agents

labels (glue, dye, solvents)

Temperature, humidity, UV light, aging

Packaging

Literature

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GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

The documentation shall contain information for the demonstration of **conformity with the general safety and performance requirements** set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements.

→ Checklist in tabular form!
Risk

- Lifecycle risk management

Benefit

- Challenge clinical data
- User acceptance

AUDIT PITFALL:
RISK BENEFIT WITHOUT CER
BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

The documentation shall contain information on:

• The benefit-risk analysis
• The solutions adopted and the results of the risk management
PRODUCT VERIFICATION AND VALIDATION

• The documentation shall contain the results of all verifications and validation tests and/or studies undertaken to demonstrate conformity with the requirements of the MDR.

6.1 Pre-clinical and clinical data

• results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications
CURRENT
• REAL STANDARD

AUDIT PITFALL:
GAP TO CURRENT STANDARD NOT EVALUATED

HARMONIZATION
• EXISTING DOCUMENTS
PRODUCT VERIFICATION AND VALIDATION

Detailed discussion of test design, test protocols and reports with data analysis and conclusions in particular for the following:

• biocompatibility
• physical, chemical and microbiological characterization
• electrical safety and electromagnetic compatibility
• software verification and validation
• stability, including shelf life
• performance and safety
PRODUCT VERIFICATION AND VALIDATION

- the clinical evaluation report
- the clinical evaluation plan
- the PMCF plan
- PMCF evaluation report
FINDING PITFALL:
PMCF NOT DETAILED

FINDING PITFALL:
DECLARATION OF INTEREST (CER)

FINDING PITFALL:
MISSING INDICATIONS

PMCF plan

clinical evaluation report

PMCF evaluation report
PRODUCT VERIFICATION AND VALIDATION

Additional information for specific cases:
• Medicinal substances
• Requirements for devices utilizing tissues or cells of human or animal origin or their derivatives
• Devices composed of substances or combinations thereof intended to be introduced into the human body that are absorbed by or locally dispersed
• ‘CMR’ and endocrine-disrupting substances
• Sterility and microbiological condition
• Measuring Function
• Devices connected to other devices
Type Testing

- Type Tests
  - Homecare
  - Collaterals
    - Alarm
    - Emergency
  - Electrical Safety
    - Costs: 20k€
  - Cytotox
  - Chemical Character
    - Cost: 20k€ - 100k€
  - Biological Safety
    - Sterility
    - Usability
      - Costs: 5k€
      - ISO14xxx
    - 60601-2-x
    - 80601-2-x
    - Product relevant standards
    - Costs: each 8k€
  - Irritation
  - Sensitation
  - Costs: each 5k€

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Collecting data sheets is not sufficient.
be compliant

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