Lübeck Summer Academy

Add value.
Inspire trust.

Aspects of the European and German Regulatory Framework for Medical Devices - A Notified Bodies' Perspective

Julia Hoyer

Speaker

Julia Hoyer

Head of Regulatory Affairs,
Medical Health Services

Focal areas: Regulatory environment medical devices

Email: julia.hoyer@tuvsud.com

Website: www.tuvsud.com/de-mdr

LinkedIn: https://www.linkedin.com/in/julia-hoyer-24a16898/

Agenda

1	Experience of first conformity assessments & our expectations
2	Missing guidance - an issue?
3	Take home message

General Workflow

Application Phase – Information from manufacturer

Application Phase – Information from manufacturer

Application Phase

- Definition Product / System
- Classification – incl. Rule and Indent
- Intended Purpose vs. Indications
- Basic UDI-DI
- Codes – MDA/MDN/MDS/MDT
- Product Description
- Facilities & Suppliers

MDR Art. 1(4): …medical devices, accessories for medical devices, and products listed in Annex XVI to which this Regulation applies pursuant to paragraph 2 shall hereinafter be referred to as ***'devices'.***

Again - What is this Basic UDI-DI ?

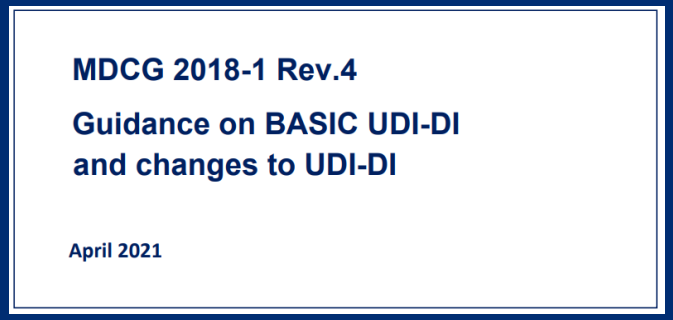
MDCG tried to help with a guidance: MDCG 2018-1v4

The Basic UDI-DI

The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics.

It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item.

Any Basic UDI-DI shall identify the devices covered by that Basic UDI-DI in a unique manner.



These devices under a Basic UDI-DI are characterized by:

- same intended purpose
- same risk class
- same essential design
- same manufacturing characteristics

Experiences with the Basic UDI-DI at class IIa/IIb

These devices under a Basic UDI-DI are characterized by:

- *same intended **purpose*** → quite clear
- *same risk class* → quite clear
- *same essential design* → huge interpretation variations experienced
- *same manufacturing characteristics* → huge interpretation variations experienced

Currently, unfortunately there is no official clearer definition of

- ***„same essential design“***
- ***„same manufacturing characteristics“***

Lots of discussions to find a harmonized view.

Also the NBs asked for clarification on EU level (MDCG), so far no information.

Therefore, the following is proposed to be used within TUV as a bridge until further clarification is given by officials:

Experiences with the Basic UDI-DI at class IIa/IIb? – MDR

- ***same manufacturing characteristics***
  - Here the horizontal codes of the commission implementing regulation (EU) 2017/2185 might be helpful:
    i. MDT codes – *Devices for which specific technologies or processes are used*
    ii. MDS codes – *Devices with specific characteristics*

SAMPLES

MDT 2001	Devices manufactured using **metal processing**
MDT 2002	Devices manufactured using **plastic processing**
MDT 2005	Devices manufactured using **biotechnology**
MDT 2006	Devices manufactured using **chemical processing**

MDS 1001	Devices incorporating medicinal substances
MDS 1002	Devices manufactured utilising tissues or cells of human origin, or their derivatives
MDS 1003	Devices manufactured utilising tissues or cells of animal origin, or their derivatives
MDS 1005	**Devices in sterile condition**
MDS 1007	Devices incorporating or **consisting of nanomaterial**
MDS 1008	**Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body**
MDS 1009	Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices

Experiences with the Basic UDI-DI at class IIa/IIb? – MDR

- ***same essential design***
  - Up to now, it **could** be
    i. same essential design elements
    ii. same essential (main?) construction characteristics
    iii. same principals of design
    iv. same substantial design features

    Yet, there is no 100% clear demarcation

Experiences with the Basic UDI-DI at class IIa/IIb?

Experienced samples and consequences of Basic UDI-DI implementation:

Extreme #1:
Devices with complete different raw materials and design features are covered by the manufacturer under 1 Basic UDI-DI

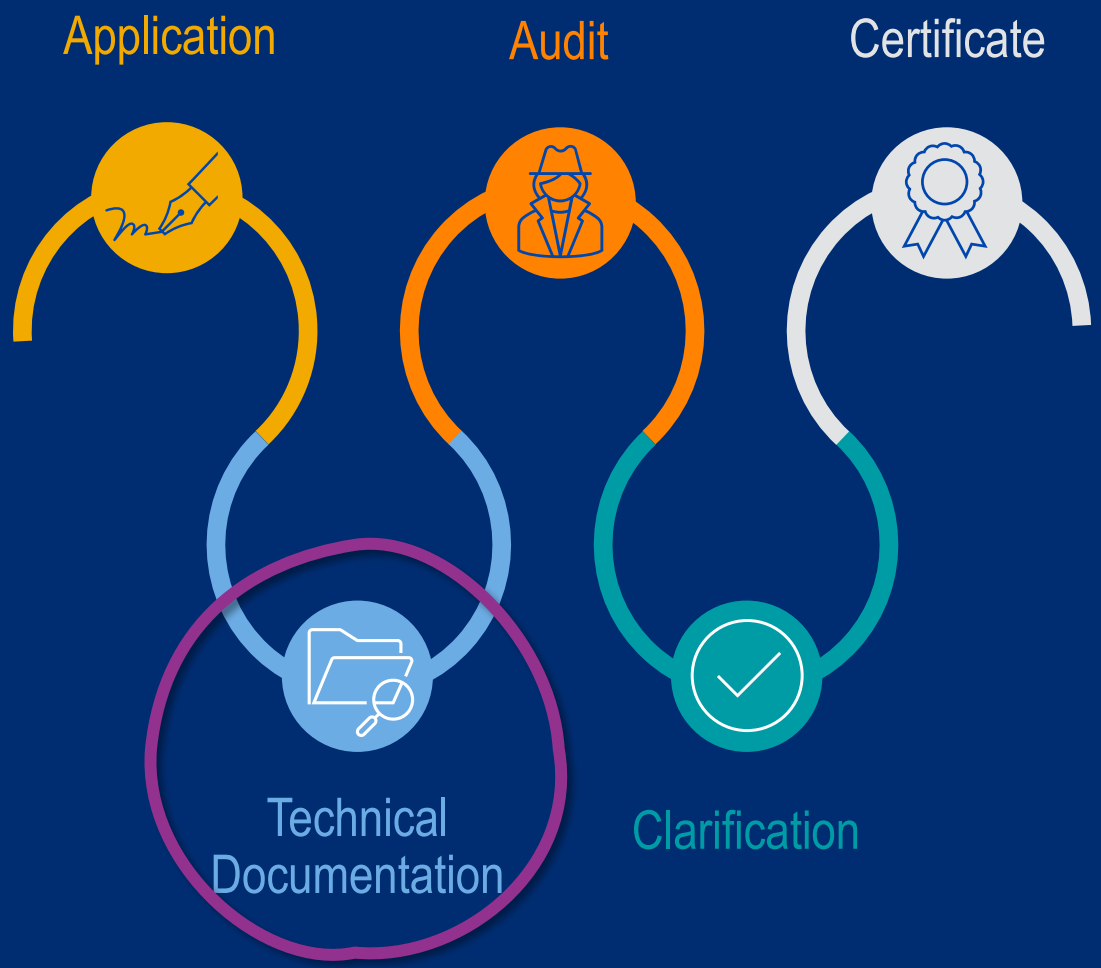
Consequence:
- → all variants under the Basic UDI-DI need to be covered in the TD assessment.
- → Meaning - initial calculation might not be correct in terms of time/effort. The TD assessment might need to be split in the middle of the project. Or the TD assessment report remains as one but needs several variant specific chapters… cannot be the intention by MDR/IVDR and will delay in an extreme way the TD assessment.

Extreme #2:
Manufacturer decided that every article (REF) of Class IIb gets its own Basic UDI-DI, even if there are several single devices matching with the 4 characteristics above

Consequence:
During the validity of a certificate – max. 5 years – the NB shall sample a certain percentage* of the „devices" (Basic UDI-DIs) from MDN/MDA and EMDN codes covered by the certificate.
In case the number of Basic UDI-DIs is raised in that artificial way that the NB needs to „over sample" the manufacturers portfolio.

*percentage – as in MDCG 2019-13

Manufacturers have to scrutinize their implementation of the Basic UDI-DI


Application
Audit
Certificate
Technical Documentation
Clarification

TD Assessment

TD Assessment

1. TD structure not covering Annex II & III requirements

2. Missing documents:
   - Promotional material
   - Process data

3. Content:
   - Essential Requirements
   - Scope of documents (CER)
   - Verification / Validation methods
   - Documented evidence missing
   - Information on design stages applied
   - Information on pre-clinical testing
   - Post market activities not clearly planned or provided

Initial certification audits – MDR/IVDR

Initial certification audits – MDR/IVDR - Remote ?

Audit

What hinders NBs?

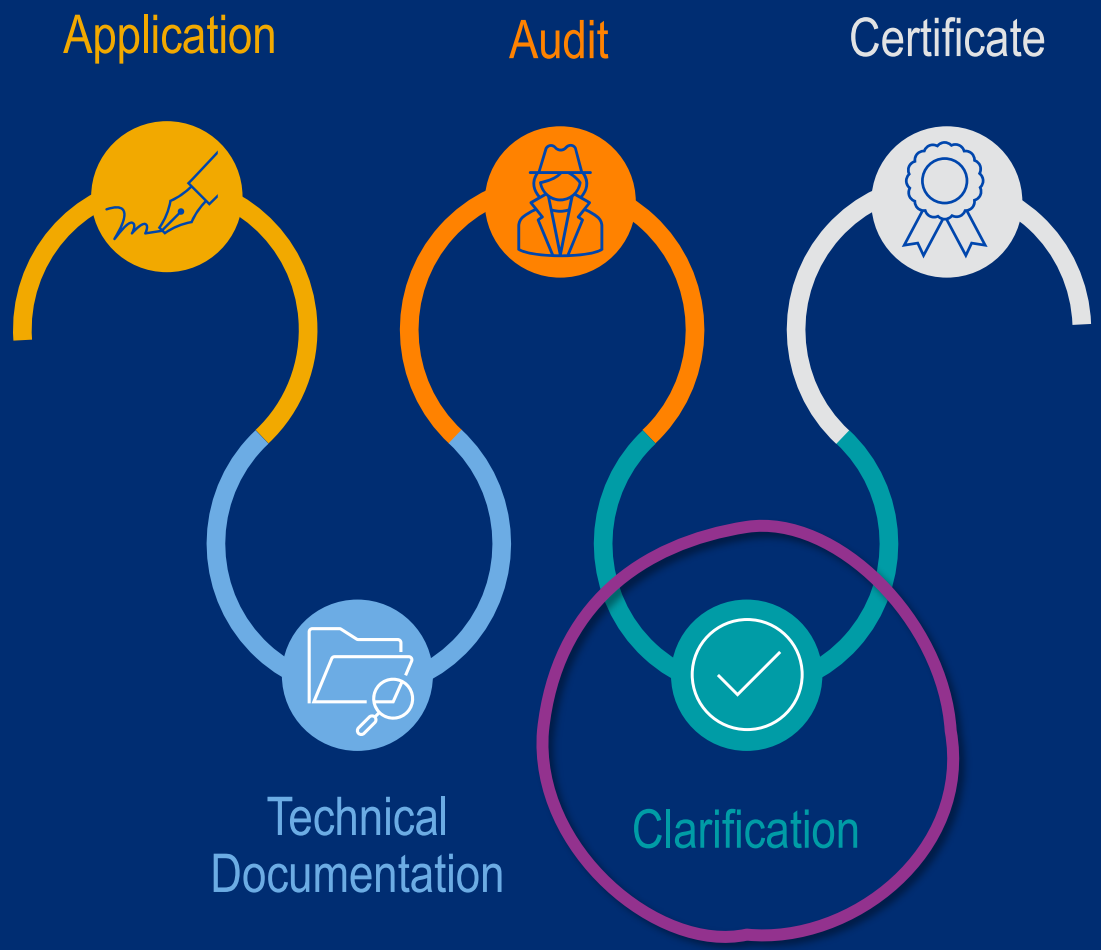
- **Legal requirements!**
  Sections 2.3 and 3.3 of Annex IX to MDR and IVDR
  2.3:..... The assessment procedure shall include **an audit on the manufacturer's premises** and, if appropriate, on the premises of the manufacturer's suppliers ….

- However, with (2021/C 8/01) Commission Notice and later member states agreed (despite contrary legal opinions) that a waiver of on-site audits in certain cases should be possible.
  BUT….a NB needs to provide an individual critical case-by-case assessment, including
  - travel restrictions and national orders
  - concrete obstacles to a safe on-site audit
  - whether the prevention of such an on-site audit could lead to products being denied access to the market or hinder their continued provision on the market
  - Compliance / risk profile of the manufacturer

Initial certification audits – MDR/IVDR – typical findings

Audit

- Person Responsible for Regulatory Compliance not defined
- No project plan for transition to MDR
- Interfaces for SRN & Eudamed not “implemented” (MDCG 2021-1 - alternatives?)
- Incident reporting insufficient
- MDR knowledge missing
- UDI System integration missing
- No awareness on Common Specifications, MDCG guidances documents


Application
Audit
Certificate
Technical Documentation
Clarification

Clarification

- “My notified body asks questions they haven’t asked before.”
- “This information is not available, please contact our supplier.”
- “This is too much information to share, we cannot provide GBs of data.”
- “Can the notified body ask this?”

Clarification

Article 53

Involvement of notified bodies in conformity assessment procedures

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned. The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure.

2. The notified body concerned shall, by means of the electronic system referred to in Article 57, inform the other notified bodies of any manufacturer that withdraws its application prior to the notified body's decision regarding the conformity assessment.

3. When applying to a notified body under paragraph 1, manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body and provide information about any previous application for the same conformity assessment that has been refused by another notified body.

4. The notified body may require any information or data from the manufacturer, which is necessary in order to properly conduct the chosen conformity assessment procedure.

5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

Article 54

Clinical evaluation consultation procedure for certain class III and class IIb devices

Top

SECTION 1 - Classification

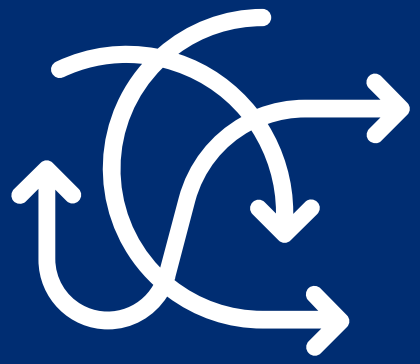
SECTION 2 - Conformity assessment

Article 52 - Conformity assessment procedures

Article 53 - Involvement of notified bodies in conformity assessment procedures

Article 54 - Clinical evaluation consultation procedure for certain class III and class IIb devices

Article 55 - Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices



- Missing guidance on:
  - Appropriate Surveillance Activities (Art. 120.3)
  - Post market surveillance requirements (PSUR?)
  - Classification
  - Vigilance
  - Harmonised reporting
  - Authorised Representatives
  - Legal status of app providers

Another wave? Again!

- Hundreds even thousands of certificates under MDD / AIMDD created until May 2021
- Validity limited to May 2024
- Manufacturer’s want to move product from MDD / AIMDD to MDR
- Resources are limited in notified bodies and manufacturers
- Amount of project will exceed the capacities in the entire eco system
- Plan carefully and ahead of time

- Resource situation remains critical in the whole eco system
- Digitalization necessary
- Keep up the communication with your Notified Body

THANK YOU !