Management of Changes under Art. 120 and MDR

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Brief overview of Notification and Management of changes

1. Requirements of notification of Changes
2. Significant Changes
3. Substantial Changes

1. Requirements of notification of Changes

Per Article 120(3) of the Medical Devices Regulation (MDR) 2017/745:
During the transition period: Medical device manufacturers should assess any changes to their device design or intended purpose to determine if they are considered **significant**.
>> No definition in the EU MDR of “significant change” but Guidance **MDCG 2020-3, Revision 1 released in May 2023**

Per Annex IX Chapter 1 (QMS) of the Medical Devices Regulation (MDR) 2017/745:
The manufacturer shall inform the NB which approved the QMS of **any plan for substantial changes** to the **quality management system**, or the **device-range covered**.
The notified body shall assess the changes proposed, determine the need for additional audits and verify whether after those changes the quality management system still meets the requirements. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits.
The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.
>> No definition in the EU MDR of “substantial change” and No MDCG

Assessment and approval of the notified body prior to the implementation of a significant or substantial change

2. Significant Changes / MDCG 2020-3, Revision 1

MDCG 2020-3, Revision 1 released in May 2023

Enhancements:

- Inclusion of changes introduced by Regulation(EU) 2023/607
- Experience gained from the application of the guidance
- Alignment with the format of MDCG 2022-6 for IVD

MDCG 2020-3, Revision 1 released in May 2023

2. Significant Changes / MDCG 2020-3, Revision 1

Significant Change - DEFINITION:

Two cumulative events:

A significant change in the design or intended purpose consist of two cumulative elements:

- there is a change in the design or intended purpose, **and**
- the change is significant.

Changes not concerning the design and intended purpose (new Section 4.2):

Qualifies what are not changes in design or intended purpose: Organization changes (administrative), manufacturing changes (even affecting labeling)

- Manufacturer's name or address change, or legal form (merger, acquisition)
- EU Authorized Representative chnage
- Relocation of manufacturing activities (including CM)
- Scale-up of manufacturing
- changes in monitoring and control of product and operations environment

MDCG 2020-3, Revision 1 released in May 2023

2. Significant Changes / MDCG 2020-3, Revision 1

What has changed with the charts?

Before applying the charts: To consider First

- corrective actions (per definition of Article 2(67) MDR) >> If accepted by CA
- Correction of spelling/merely editorial changes to label/IFU
- Update to Label/IFU/Implant Card required by other EU legislation
- clarifications of intended purpose, population, clinical application

→ **Not Significant**

For Decision E (sterilization/Packaging): Shelf-Life was added for clarity

2. Significant Changes / MDCG 2020-3, Revision 1

Why consult the guidance?

Revision 1 is replete with examples >> based on experience from the MDR and application of this MDCG guidance by NBs and Manufacturers

Addition of examples of non-significant or significant change in

- Intended purpose
- Design
- Software changes
- Substance or material
- Sterilization

Easier interpretation >> To be read together with the sub-flowcharts in Appendices

Justification based on Risk >> The conclusion that a change is "non-significant" must be made based on the impact of the change does not affect negatively the benefit/risk ratio

3. Substantial Changes

Being not significant does not mean it is not substantial

No MDCG Guidance

Follow the procedure agreed with your Notified Body

- Applicable for Legacy devices under EU MDD with active EU MDD Certificate
- Applicable for devices CE Marked under EU MDR

Provisions integrated within your QMS

- Change control process (QMS, design, …)
- Verified during audit >> Selection of notified and non-notified changes (QMS and product-related)

Notification of Changes to Notified Body

- **Requirements** :
  - Manufacturer's obligation to declare substantial / significant changes to the Notified Body
  - The manufacturer must justify the nature of the change

- **When to notify?**
  - After the application for certification and before certificate is issued
  - After certificate has been issued
  - Between 2 services (i.e. between 2 surveillance audits)

MDCG 2020-3, Revision 1 released in May 2023

Notification of Changes to Notified Body

- **Criteria for determining the assessment "route"**:
  - Type of modification
  - Varies based on the conformity assessment procedure applied
  - Varies on the Classification of the device impacted
  - Varies if there is introduction of new technology applied

- **Assessment "route" ?**
  - Additional audit
  - Assessment of the Technical Documentation
  - Sampling plan update

Significant and Substantial Changes require APPROVAL by Notified Body prior to its implementation

Thank you for your attention.

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