Conformity Assessment of Medical Devices Under The New MDR

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Agenda

- Scope: MDR Article 1 and 2

- MDR Conformity Assessment:
  - MHRA* (UK Competent Authority)
  - MDR Annex IX, X, XI

- Class I, IIA, IIB, III and Custom Made Devices

- Must Know

- What requirements need to be met for a conformity assessment?

- Summary

*Medicines and Healthcare Products Agency
Scope of the new MDR - Article 1

[1.] This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. This Regulation also applies to clinical investigations concerning such medical devices and accessories conducted in the Union.

[2.] This Regulation shall also apply, as from the date of application of common specifications adopted pursuant to Article 9, to the groups of products without an intended medical purpose that are listed in Annex XVI, e.g. contact lenses; equipment for liposuction; infra-red, visible light and ultra-violet emitting equipment; equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields; substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction.

[3.] Devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose.
Scope of the new MDR - Article 2

“Medical device” means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
MDR Conformity Assessment

ANNEX VIII CLASSIFICATION RULES
- CHAPTER I Definitions specific to classification rules
- CHAPTER II Implementing rules
- CHAPTER III Classification rules

ANNEX IX CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION
- CHAPTER I Quality Management System
- CHAPTER II Assessment of the technical documentation
- CHAPTER III Administrative provisions

ANNEX X CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION

ANNEX XI CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION
- PART A Production quality assurance
- PART B Product verification
Device Classification

**Class I**
- Medical Devices: Wheelchairs, spectacles
- In Vitro Diagnostic Medical Devices: Clinical chemistry analysers

**Class IIa**
- Medical Devices: Dental fillings, surgical clamps, tracheotomy tubes
- In Vitro Diagnostic Medical Devices: Pregnancy self-testing, urine test strips, cholesterol self-testing

**Class IIb**
- Medical Devices: Condoms, lung ventilators, bone fixation plates
- In Vitro Diagnostic Medical Devices: Blood glucose self-testing, PSA screening, HLA typing

**Class III**
- Medical Devices: Pacemakers, heart valves, implanted cerebral simulators
- In Vitro Diagnostic Medical Devices: Hepatitis B blood donor screening, HIV blood diagnostic test, ABO blood grouping

**Class A**
- Medical Devices: Prepared selective culture media
- In Vitro Diagnostic Medical Devices: Specimen collection devices

**Class B**
- Medical Devices: Specimens, dressings
- In Vitro Diagnostic Medical Devices: Specimen collection devices

**Class C**
- Medical Devices: Antiseptic preparations, wet dressings
- In Vitro Diagnostic Medical Devices: Antiseptic preparations, wet dressings

**Class D**
- Medical Devices: Antiseptic preparations, wet dressings
- In Vitro Diagnostic Medical Devices: Antiseptic preparations, wet dressings

**Notified Body approval required**
- High risk

**Self-assessment**
- Low risk
Classification – Conformity Assessment

Medical Devices

- **Low risk**
  - Class I

- **Self-assessment**
  - Class IIa

- **Notified Body approval required**
  - Class IIb
  - Class III

In Vitro Diagnostic Medical Devices

- **High risk**
  - Class D
  - Class C
  - Class B

**Which classes of products require conformity assessment by a notified body?**

Approval is required for Class IIa, IIb and III medical devices and Class B, C and D in vitro diagnostic devices.

Some Class I and Class A devices will require notified body approval for parts of the manufacturing process that relates to sterility or metrology, if the medical device includes sterile products or a measuring function.

Manufacturers can certify their products with any notified body within the EU.
Annex IX Conformity Assessment Based On A Quality Management System And On Assessment Of Technical Documentation

- Quality management system assessment: application with NB and Notified Body access to the technical documentation

- Quality management system audit: including technical documentation assessment for devices selected on a representative basis per published guidance developed by the MDCG*

-> Notified Body documents its rationale for the samples taken.

- Assessment of the technical documentation: special assessment procedures for certain class III and class IIb devices** require that NB transmits a clinical evaluation assessment report, along with the manufacturer's clinical evaluation documentation, to the Commission for transmission to the relevant expert panel; NB to seek scientific opinion from a competent authority or EMA, change assessment, and batch verification based on official certificates issued by a Member State laboratory or a designated laboratory or description of ADME and other properties where applicable

*Medical Device Coordination Group
**e.g. devices incorporating a medicinal substance, devices incorporating human blood or plasma derivative or a substance that, if used separately, may be considered to be a medicinal product, devices manufactured utilizing derivatives of tissues or cells of human origin, devices manufactured utilizing animal tissue rendered non-viable or utilizing non-viable products derived from animal tissue, devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body
Annex IX Conformity Assessment Based On A Quality Management System And On Assessment Of Technical Documentation

- Assessment of substantial changes to the quality management system or the device-range covered

- Surveillance assessment: Audits at least once every 12 months including manufacturer's suppliers and/or subcontractors; unannounced audits randomly performed at least once every five years on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors combined with the periodic surveillance assessment or be performed in addition; surveillance assessment to include an assessment of the technical documentation (class IIa/IIb devices) or a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices (class III).
Annex X Assessment Based On Type-Examination

EU type-examination is the procedure whereby a Notified Body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the device production envisaged, fulfils the relevant provisions of this Regulation.

- Application with NB
- NB assessment of technical documentation
- NB review the clinical evidence
- NB to carry out or arrange for the appropriate assessments and the physical or laboratory tests
- Change assessment
Annex XI Conformity Assessment Based On Product Conformity Verification

The objective of the conformity assessment based on product conformity verification is to ensure that devices conform to the type for which an EU type-examination certificate has been issued, and that they meet the provisions of this Regulation which apply to them.

PART A PRODUCTION QUALITY ASSURANCE
- Quality management system assessment: application with NB
- Surveillance assessment as in Annex IX
- Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma as in Annex IX
- EU declaration of conformity by manufacturer and technical documentation assessment by NB for the devices selected on a representative basis
Annex XI Conformity Assessment Based On Product Conformity Verification

PART B PRODUCT VERIFICATION

Product verification shall be understood to be the procedure whereby after examination of every manufactured device, the manufacturer, by issuing an EU declaration of conformity in accordance with Article 19 and Annex IV, shall be deemed to ensure and to declare that the devices which have been subject to the procedure set out in Sections 14 and 15 conform to the type described in the EU type-examination certificate and meet the requirements of this Regulation which apply to them.

Verification by examination and testing of every product or batch verification of each batch in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma.
Must know

The requirement for manufacturers to conduct a conformity assessment before placing their device on the market, and for higher risk devices to involve a Notified Body, is unchanged.
Class I devices:

Similar to the current MDD Annex VII “EC declaration of conformity”.
- New EU Declaration of Conformity (new Article 19) prepared by manufacturer,

- Fulfill general obligations of all manufacturers (new Article 10),

- Involvement of a Notified Body is limited for Class I devices, and only required for
  - sterile devices,
  - reusable surgical instruments or
  - devices with a measuring function.
Class IIa devices:

Similar to the current MDD, manufacturers of Class IIa devices have the option of following the same conformity assessment route as for Class IIb devices, the new EU MDR’s Annex IX, with the Notified Body only assessing representative technical documentation.

Manufacturers may choose not to follow the full quality management system approach essentially similar to the current MDD’s Annex VII “EC declaration of Conformity” combined with either Annex IV or Annex V:
- Compile the new technical documentation (new Annex II)
- Manufacturer prepares the new “EU declaration of conformity” (new Article 19)
- and then the Notified Body either:
  - (a) assesses the Technical Documentation of a representative sample of the devices (Annex XI, Part A, Section 10),
  - or (b) carries out tests to confirm the conformity of the devices (Annex XI, Part B, Section 18).
Class IIb devices:

Similar to the current MDD, manufacturers of Class IIb devices have the option of following the same conformity assessment route as for Class III devices, the new EU MDR’s Annex IX with the difference that the Notified Body is only required to assess the technical documentation of at least one representative device of each generic device group produced by the manufacturer.

As with the current MDD, there are alternative routes for manufacturers of Class IIb devices who chose not to follow the full quality management system approach. These are the same as those for Class III devices with one fewer alternative available to manufacturers of Class IIb devices compared to the MDD: there is no equivalent to the MDD’s Annex VI “product quality assurance”. Manufacturers currently following this route will have to choose an option from the new Annex XI. Either Part A, “Production Quality Assurance”, or Part B, “Product Verification”.
Class III devices:

The current MDD’s Annex II “full quality assurance” route will be replaced by the new EU MDR’s Annex IX “conformity assessment based on quality management system assurance and assessment of the technical documentation”.

There are alternatives for those manufacturers who chose not to follow the full quality management system approach: the current MDD alternative for Class III devices of Annex III “EC type-examination”, combined with either Annex IV “EC verification” or Annex V “production quality assurance” will be replaced by the new EU MDR’s Annex X “conformity assessment based on type examination” combined with new Annex XI “conformity assessment based on product conformity verification”.

This is essentially identical to those of the current MDD. The new EU MDR’s Annex XI “conformity assessment based on product conformity verification” includes both the MDD’s current options; Part A being the new “Production Quality Assurance” route, replacing the current MDD’s Annex V “production quality assurance”. Part B being the new “Product Verification” route, replacing the current MDD’s Annex IV “EC verification”.
Custom made devices:

Unlike the current MDD where the requirements for custom made devices are part of the current MDD Annex VIII the new EU MDR has a dedicated Annex, Annex XIII “procedure for custom made devices”. However, the requirements to draw up a statement about the device and keep records etc. are fundamentally the same as in the current MDD.

The exception being class III custom made devices, where a quality system assessment by a Notified Body is required; either the “quality management system assessment” of the new Annex IX, Chapter 1 or the “Production Quality Assurance” of the new Annex XI, Part A.
MDR Conformity Assessment Procedure CLASS I

- Annex I: General Safety and Performance Requirements
- Annex II: Technical Documentation
- Annex IV: EU Declaration of Conformity
- Annex VI: UDI – Unique Device Identification
- Annex VIII: Classification Rules
MDR Conformity Assessment Procedure CLASS IIa

Annex I  General Safety and Performance Requirements
Annex II  Technical Documentation
Annex III  Technical Documentation on Post Market Surveillance
Annex IV  EU Declaration of Conformity
Annex V  UDI – Unique Device Identification
Annex VIII  Classification Rules

Annex IX  Technical Documentation
Quality Management System (EN ISO 13485)

Annex X  Part A  Production and Quality Assurance (EN ISO 13485)
Annex X  Part B  Product Verification

CE  CE 0482
What requirements need to be met for a conformity assessment?

1. General Safety and Performance Requirements (Annex I MDR):
   - Benefits must outweigh risks and achieve claimed performance supported by clinical evidence and investigation
   - Chemical, physical and biological properties for medical devices disclosed
   - [Performance characteristics for ivds disclosed]
   - Information supplied by manufacturer with the device; e.g. IFU and correct device labelling

2. Technical documentation (Annex II MDR)

3. Harmonized standards / common specifications (Articles 8 and 9 MDR)
See Annex IX, X and XI of MDR for details
Summary

1. Pass a conformity assessment
   This does not apply to most Class I medical devices and Class A in vitro diagnostic devices

2. Draw up a declaration of conformity (Annex IV of the MDR and IVDR)

3. Place a CE mark on the device
   CE marks are not unique to medical devices

4. Assign a Basic UDI-DI and provide it to the UDI database
   For devices other than custom-made devices

5. Submit key information about the manufacturer, and authorised representative and importer if applicable, to the electronic system (Eudamed)
   For devices other than custom-made devices

6. Place your CE marked device anywhere in Europe or put your device into service
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