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OVERVIEW OF REQUIREMENTS RELATED TO ART 120(3) OF MDR 2017/745

POST-MARKET SURVEILLANCE UNDER EU MDR

INTERTEK MEDICAL NOTIFIED BODY - LESSONS LEARNED SINCE MDR'S IMPLEMENTATION

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AGENDA

01 **Transitional provisions under Article 120 (3)**

02 **Post market requirements for devices with MDD certificate**

03 **MDR 2017/745 Post Market Surveillance requirements**

04 **Intertek Medical Notified Body - Lessons Learned Since MDR's Implementation**

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TRANSITIONAL PROVISIONS UNDER ARTICLE 120 (3)

BACKGROUND MDR 2017/745

- The MDR will replace the existing Medical Devices Directive (93/42/EEC) (MDD) and the Active Implantable Medical Devices Directive (90/385/EEC) (AIMDD).

- In contrast to Directives, Regulations do not need to be transposed into national law. This will therefore reduce the risks of discrepancies in interpretation across the EU market.

- The MDR was published in May 2017, marking the start of a period of transition from the MDD and the AIMDD.

- The transitional period will end on 26 May 2021, the “Date of Application” (DoA) of the Regulation. From that date the MDR applied fully.

BACKGROUND ART 120 (3)

- A device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/ EEC may only be placed on the market or put into service provided that from the date of application of the Regulation 2017/745 it continues to comply with either of those Directives and provided there are **No significant changes in the design and intended purpose**.

- The requirements of the Regulation relating to **post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices** shall apply in place of the corresponding requirements in those Directives.
- The notified body that issued the certificate shall continue to be responsible for the **appropriate surveillance** in respect of all of the applicable requirements relating to the devices it has certified.
- Article 120 presents more details of the requirements applicable to both Economic Operator and Notified Body as regards to transitional provisions.

TRANSITIONAL PROVISIONS

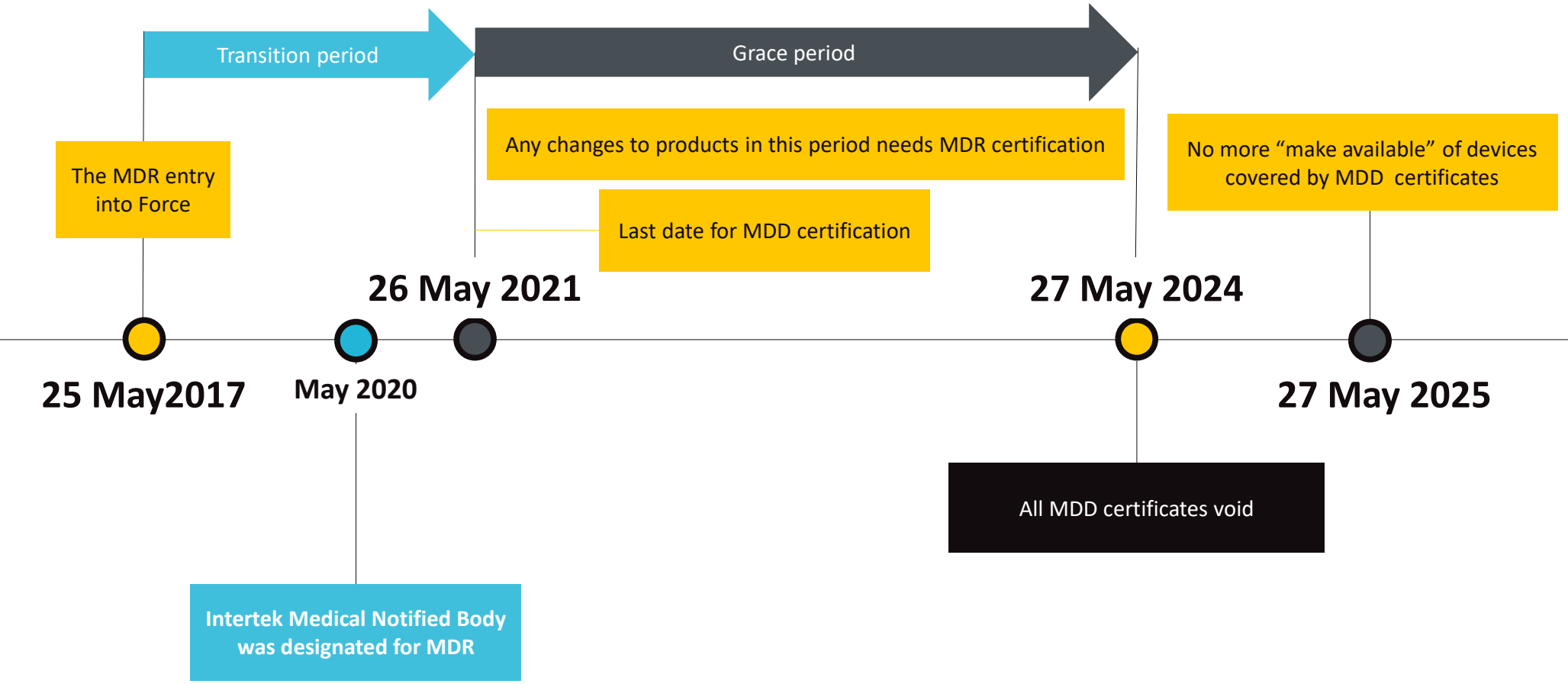
Several transitional provisions are in place (Article 120).

Some devices with certificates issued under the Directives (AIMDD/MDD certificates) may continue to be “placed on the market” until 27 May 2024, and “made available” until 27 May 2025.

- Placing on the market means “the first making available of a device, other than an investigational device, on the Union market”
- Making available on the market means “any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge”

During the transition phase, products certified under the MDD and products certified under the MDR will coexist on the market.

TRANSITION TIMELINES MDR (ARTICLE 120 OF EU REGULATION 745/2017)



“SELL-OFF” PROVISION

- The “sell-off” provision is intended to limit the time during which devices that are compliant with the Directives and have already been placed on the market may be made available.

- Any devices that are still within the supply chain and that have not reached their final user as being ready for use, for example a hospital, on 27 May 2025 are no longer marketable.

- Once a Directive-compliant device has been made available to the final user by the deadline, the further making available of this device is not subject to/covered by the Regulation.

CONSIDERATIONS FOR MDD APPROPRIATE SURVEILLANCE UNTIL MAY 2024

IMPORTANT considerations

- No significant changes to product design or intended purpose are allowed

What do the manufacturer need to consider in their QMS

- Post Market Surveillance - Article 83-86, 92
- Vigilance - Article 87-92
- Registration of Economic Operators - Article 31
- Registration of Devices - Article 29
- Market Surveillance - Article 93-100

CONSIDERATIONS FOR APPROPRIATE SURVEILLANCE UNTIL MAY 2024

Technical documentation

Technical documentation on post-market surveillance Annex III and articles 83 to 87 of the MDR

- Conclusions of benefit-risk determination (art.83)
  - Risk Management
  - Clinical Evaluation
  - State of the Art
- Information concerning serious incidents and FSCA (art.87)
- Records referring to non-serious incidents and data on any undesirable side-effects
- Information from trend reporting
- Relevant specialist or technical literature, databases and/or registries
- Information including feedback and complaints provided by users, distributors and importers
- Publicly available information about similar medical devices
- Main findings of PMCF
- Volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and where practicable the usage frequency of the device

MDD SURVEILLANCE ACTIVITIES WILL CONTINUE

- Technical documentation sampling will continue as normal as per MDD and MEDDEV until further notice.
- Technical assessments will be carried out under the MDD, assessment of the post market surveillance shall be carried out in accordance with Annex III of the Regulation 2017/745 accordingly.
- Surveillance audits will continue as normal as per MDD, 0.5 audit days will be added to verify the compliance with Regulation 2017/745 in terms of the post-market surveillance activities.
- Unannounced audits will continue under MDD there will however be less frequent UAs under MDD
- Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to 26 May 2020 may continue to be conducted. As of 26 May 2021, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with the Regulation.

SIGNIFICANT CHANGES MDR ART. 120 (3)

MDR Article 120(3).

- No significant changes in design or intended purpose of a device can be performed after the date of application of the MDR under MDR Article 120(3).
- “Significant change in design or intended purpose” under MDR Article 120(3), the implementation of such a change would prevent the manufacturer from continuing to place that device on the market under the Directives.
- Qualification of a change as “significant” according to Art. 120 (3) MDR shall be determined on a case-by-case basis.

What is a significant changes? Examples listed below:

- Change of the Intended Purpose
- Change of the design or performance specification
- Software Change
- Change of a Material
- Change of terminal sterilization method of device
- Change to packaging design with impact to the sterilization
- Change of a Design change related to corrective actions
- Material that is used to make or compose the device

POST MARKET SURVEILLANCE FOR DEVICES WITH MDD CERTIFICATE

POST MARKET SURVEILLANCE – REQUIREMENTS

- MDD – conformity annexes (II, III, VII)
- *MedDev 2.12/1 (rev 8) – Guidelines on a Medical Devices Vigilance System*
- MedDev 2.12/2 (rev 2) – Post Market Clinical Follow Up Studies: A Guide for Manufacturers and Notified Bodies

MDR

- Chapter VII: Post-Market Surveillance, Vigilance and Market Surveillance
- Annex III: Technical Documentation on Post-Market Surveillance
- Annex XIV (Part B): Post Market Clinical Follow Up

PMS – WHAT'S CHANGING FROM MDD TO MDR?

- Requirements are more explicit and prescriptive with respect to:
  - What data should be gathered
  - How it should be gathered
  - How it should be used
  - Timescales for updates, review and validation
- New requirements for publicly available information and sharing of information across Member States

PMS - Annex III (1a):

- Serious incidents, FSCA, information from PSURs
- Non-serious incidents and data on any undesirable side-effects
- Sales, complaints and trend reporting
- Data from literature, databases and/or registers
- Other market feedback (eg provided by users, distributors and importers)
- Publicly available information on similar medical devices

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PMS - Annex III (1b):

- Proactive and systematic
- Enable comparison with similar devices on the market
- Methods to assess the data, including indicators and threshold values
- Statistical methods for trending and monitoring increases in frequency or severity of incidents
- Protocols for communication with CA, NB, EO & users
- Procedures for corrective actions

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PMS - Article 83(3):
PMS data shall be used to:
- Update the benefit-risk determination, technical documentation, IFU, labelling, clinical evaluation, SSCP
- Improve risk management
- Identify needs for CAPAs or FSCA;
- Identify options to improve the usability, performance and safety of the device
- Contribute to the post-market surveillance of other devices (where relevant)
- Detect and report trends

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For Class III and implantable devices, **PMCF** report is updated at least annually (Article 61(11))

MDR 2017/745 POST MARKET SURVEILLANCE REQUIREMENTS

WHAT IS POST MARKET SURVEILLANCE UNDER MDR?

'Post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive
actions;

Post-market surveillance ≠ Market Surveillance

'Market surveillance' means the activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonization legislation and do not endanger health, safety or any other aspect of public interest protection;

ELEMENTS OF POST-MARKET SURVEILLANCE

Art. l 5: Person Responsible for Regulatory Compliance
Art. 83: Post-market surveillance system of the manufacturer

Includes internal PmS, vigilance and market surveillance

- Proactive
- Systemic
- Covers the entire lifetime of the device
- Interacts with Corrective and Prevention Actions processes (CAPAs)

PMS is part of the manufacturer's QMS

Art. 84: PMS Plan
Art. 85: PMS Report
Annex Ill : Technical Documentation for PMS
Art. 86: PSUR
Art. 87: Reporting of serious incidents & FSCAs
Art. 88: Trend Reporting
Art.89: Analysis of serious incidents & FSCAs
Annex XIV, part B: PmCF

SOURCES OF DATA FOR POST-MARKET SURVEILLANCE

Proactive sources of data

- Written or electronic surveys or questionnaires
- Literature reviews
- Use of medical device registries
- Post-market clinical follow-up studies, i.e. clinical investigations
- Vigilance-related information published by Regulatory authorities including but not limited to recalls, field safety notices , alerts etc.
- Manufacturer-sponsored device tracking/implant registries
- Expert user groups (focus groups)

Reactive sources of data

- Review of complaints, including incident reports, including those coming from in-house testing (if applicable)
- Unsolicited user feedback and/or observations (other than complaints) by healthcare professionals and/or any other Stakeholders coming into the attention of Sales and/or
- marketing Departments of manufacturers
- Review of maintenance/service reports
- Review of regulatory compliance notifications

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

- **Art.32**: The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of a medical device.
- It is only applicable to implantable devices (Ila as well) and class Ill devices, other than custom-made or investigational devices
- Key role in the post-market clinical follow-up aligned at all times with TechDoc
- For the following devices, the SSCP will have a part intended for patients:
  - Implantable devices for which patients will be given implant cards
  - Class Ill devices that are intended to be used directly by patients.
  - Devices listed in MDR Annex XVI

The SSCP has to be validated by the Notified Body (NB) – refer to MDCG 2019-9

When EUDAMED is made available, SSCPs will be publicly available

Translations to EU languages

- The SSCP should be translated into the languages accepted in the member States where the device is envisaged to be sold similarly to IFU [Annex II (2), Art . l 0, par. l l]
- Translation in English is mandatory

Article 32

Summary of safety and clinical performance

1. For implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance.

The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.

The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary is available.

2. The summary of safety and clinical performance shall include at least the following aspects:

(a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN;

(b) the intended purpose of the device and any indications, contraindications and target populations;

(c) a description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device;

(d) possible diagnostic or therapeutic alternatives;

(e) reference to any harmonised standards and CS applied;

(f) the summary of clinical evaluation as referred to in Annex XIV, and relevant information on post-market clinical follow-up;

(g) suggested profile and training for users;

(h) information on any residual risks and any undesirable effects, warnings and precautions.

3. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2).

LESSONS LEARNED SINCE MDR'S IMPLEMENTATION

COMPANIES WITH AN EXISTING MDD CERTIFICATE SHOULD PURSUE MDR CERTIFICATION ASAP

There were previously more than 50 Notified Bodies certified under MDD, but less than half are currently certified under the MDR. Estimated review times are nine to 12 months, depending on the Notified Body and point of contact.

If there are questions from the Notified Body or additional testing or evidence is requested, the process is further extended, as the back and forth between the manufacturer and Notified Body is impacted.

Since the MDR certification process can be quite lengthy, it is in the manufacturer's best interest to start the process now so they have their MDR CE certificate in hand before their MDD certificate expires. The same is true for manufacturers with a new device that must be reviewed under MDR before CE marking.

Intertek Medical Notified Body- Pre-application form for MDR 2017/745 certification at Intertek Medical Notified Body https://www.intertek.com/auditing/mdr-pre-application/

MDR TECHNICAL DOCUMENTATION

The most common reasons for delays in technical documentation reviews are:

- Incomplete Submissions – All the information needed for the review is not provided
- Poor structuring of the Technical Documentation – The information is present but difficult to locate.

MDR Technical Documentation – Best Practice

- Intertek Medical Notified Body provides IMNB Technical Guidance - Outline of Requirements For Submission Of The MDR File
- A complete and well-organised technical documentation file decreases time and cost of the review.
- Searchable, bookmarked PDF files.
- The technical documentation should be available in full in accordance with Annex **II and Annex III**

Annex II Technical Documentation

1. Device Description
2. Information to be supplied by the manufacturer
3. Design and Manufacturing Information
4. General Safety and Performance Requirements
5. Benefit-Risk analysis and risk management
6. Product verification and validation

Annex III Technical Documentation on Post-Market Surveillance

- Post-Market Surveillance (PMS) Plan
- Post-Market Clinical Follow-Up (PMCF) Plan
- Periodic Safety Update Report (PSUR)

Annex XIV – Clinical Evaluation and Post-Market Clinical Follow-Up

Guidance - MDCG endorsed documents and other guidance

https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_da

This page provides a range of documents to assist stakeholders in applying Regulation (EU) 2017/745 on medical devices (MDR) EN and Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices EN. The majority of documents on this page are endorsed by the Medical Device Coordination Group (MDCG) in accordance with Article 105 of the MDR and Article 99 of the IVDR. They are drafted in collaboration with interested parties represented in the various groups and denominated by the following format: "MDCG Year-Number-revision".

Stay up to date on Medical Device Industry news with Intertek Medical Notified Body quarterly Regulatory Update newsletter - https://www.intertek.com/assurance/mdr/


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