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Regulatory Summit

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LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

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Before the implementation 26th of May 2020

Intrepretation of MDR

Guidances is developed Several EU working groups and taskforces.

No MDR manufacturer or devices has yet been inspected by MPA

MPA has a Risk based approach in market surveillance
- Signal detection
- Vigilance
- Inspections of manufacturers

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After the implementation 26th of May 2020

Contionous intrepretation of MDR
Guidances developed and work continues
Several EU working groups and taskforces
MDR includes all economic actors

MPA has a Risk based approach in Market surveillance
- Collaboration with other authorities regararding
- Signal detection
- Vigilance (continues)
- Joint Inspections, all economic actors

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MPA: Competent Authority (CA) and Designating Authority (DA)

- MPA is CA for MDD/IVD and MDR/IVDR
- MPA is DA for MDR
- MPA is participating in Joint assessment team, JAT (Notified Body)
- MPA is participating in Joint inspections/Market surveillance, JAMS (JIG)

- Swedac is supervising Notified body for MDD products/manufacturer in Sweden.

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Competent Authorities - Market Surveillance Activities

Chapter VII, section 3 Art. 93 MDR

- The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples.
- The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.
- annual surveillance activity plans, annual summary of the results of surveillance activities and make it accessible to other competent authorities.

Patient safety comes first

Chapter II -> Article 10 General obligation of manufacturers

- Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating
- Manufacturers shall conduct a clinical evaluation
- Shall draw up and keep up to date technical documentation
- Quality management system…
- "working "Vigilance system…
- ..shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities.
- A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorised representative has the necessary documentation permanently available.

Technical Documentation

The manufacturer will draw up and keep up to date the technical documentation that demonstrates the conformity of their devices with the technical requirements of the MDR. This technical documentation must be prepared according to Annex II and III

- *Qualification, risk class*
- *Description and specification*
- *Information to be supplied by the manufacturer*
- *Reference to previous generations of the device and to similar devices*
- *Design and manufacturing information*
- *General safety and performance requirements*
- *Demonstration of conformity*
- *Benefit-risk analysis (sections 1 and 8 of Annex I) and Risk management (section 3 of Annex I).*
- *Pre-clinical and Clinical evaluation data*
- *The post-market surveillance system*
- *Records*

MDCG 2019-15

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DCG 2019-15 Guidance notes for manufacturers of class I Medical devices

https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

- **Meet the general safety and performance requirements**
- **Conduct clinical evaluation**
- **Prepare technical documentation**
- **Notified body needed?**
- **Prepare instruction for use and labelling**

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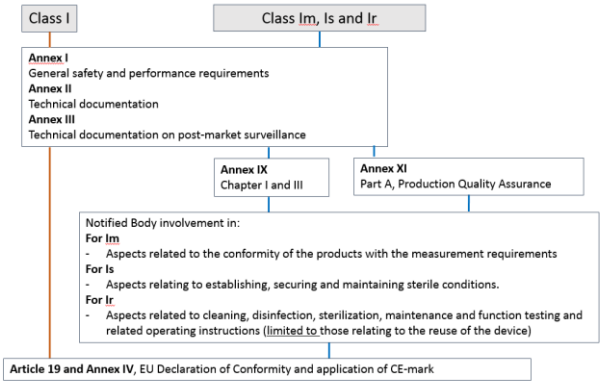
Class I, Im, Is and Ir



MDCG 2019-15

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Post -market surveillance, vigilance and market surveillance chapter VII section I and II, MDR

Post market surveillance plan, see annex III, and PSUR. Article 83 – 86 MDR

Class	Technical Doc	PMS	
Class I	√	Post market surveillance report, updated when nessesary	
Class IIa	√	Periodic safety update report PSUR updated when nessesary and at least every second year	
Class IIb	√	Periodic safety update report PSUR updated when nessesary and at least annually	
Class III	√	Periodic safety update report PSUR updated when nessesary and at least annually	
Implantable	√	Periodic safety update report PSUR updated when nessesary and at least annually	

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Post -market surveillance, vigilance and market surveillance chapter VII section I and II , MDR

Reporting of serious incidents , Field safety corrective actions , trend analysis art. 87-89

- Manufacturer shall report any serious incidents immediately; 15 days
  - if the event of death or unanticipated serious deterioration of health; 10 days
  - if serious public health threat; 2 days
- Initial report shall be followed by final report
  - if uncertain of the seriousness the manufacturer shall nevertheless submit a report

FSCA
PSR
Trend reporting - significant increase in incidents (not serious) effect on risk / benefit analysis

Changes in transitional period acc to art. 120 in MDR (**MDCG 2019-10)**

Changes in transitional period acc to corrigendum 2

- https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745R(02)&from=SV
- https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en

- MDD Certificate issued by NB will remain valid until 26 of may 2024 at the latest.

Class I devices that will be reclassified to a higher risk class according to MDR new classification rules can remain valid if the declaration of conformity is issued before 26 of may 2020

- NO SIGNIFICANT CHANGES ARE ALLOWED!

Transitional provision article 120, *Guidance is ongoing*

- MDD class I – MDR appliec from 26th of May
  Manufacturers will need tomake a new registrer at MPA declare to conform to MDR
- MDD class I reclassified to higher risk class acc. to MDR (need of a Notified body) – DoC valid if established before 26th of May.
- MDD class IIa, IIb and III certificate issued by Notified body valid as stated on certificate. including Is and Im
- *3. By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this 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.*

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Significant changes /non significant changes

Draft Guideline is circulated and commented (Guidance on significant changes under article 120 of the MDR, (devices covered by MDD/AIMD))

"Changes to the certificate is not allowed".
120(3) a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose.

Significant changes might be:
- Changes of manufacturing facilities/subcontract
- Changes in QMS, quality control, design , change in intended purpose, performance, ingredients,

As of 26 May 2020, however, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with MDR

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Usefull Links and guidelines:

- https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745R(02)&from=SV
  Corrigendum
- https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en
  General information from EU Commission
- https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en
  Published guidance documents
- https://lakemedelsverket.se/malgrupp/Foretag/Medicinteknik---ny-lagstiftning/
  Samlad information på LV hemsida.
- https://lakemedelsverket.se/overgripande/Publikationer/Nyhetsbrev/Medicinteknik/
  Nyhetsbrev från Medicinteknik, prenumerera gärna

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