EU Medical Device Regulations, Notified Body overview and update from BSI

By Royal Charter

Topics

- MDR/IVDR Recent Developments
- BSI NB Update

Key Changes within MDR/IVDR

MDR

- Several new devices/products in scope
- Several up-classifications
- Increased emphasis on clinical data
- Oversight by expert panels

IVDR

- New classification system
- More NB involvement compared to IVDD
- Increased emphasis on performance evaluation
- Introduction of EU Reference Labs

Increased Technical Documentation requirements
Increased post-market requirements
Increased Transparency - EUDAMED

Focusing a bit more on MDR..and as a reminder..

- The following devices/products need MDR certificates by 26 May 2020 for continued market viability

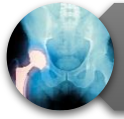

Class I re-usable surgical instruments


Software that was Class I under MDD and now up-classified


Devices utilising Human-tissue derivatives


Devices without a medical purpose – Annex XVI


Article 117 Drug/Device combinations


Custom-made Class III implants

~6 months left!

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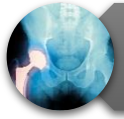
Custom-made Class III implants

An extension to May 2024 has been **proposed** in the text of the second corrigendum;
No official confirmation yet

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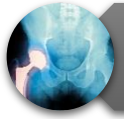
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More guidance in the MDCG Guidance document 2019-11

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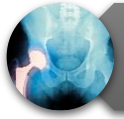
Custom-made Class III implants

Commenting period closed on the draft Common Specification; Expected to be published early 2020

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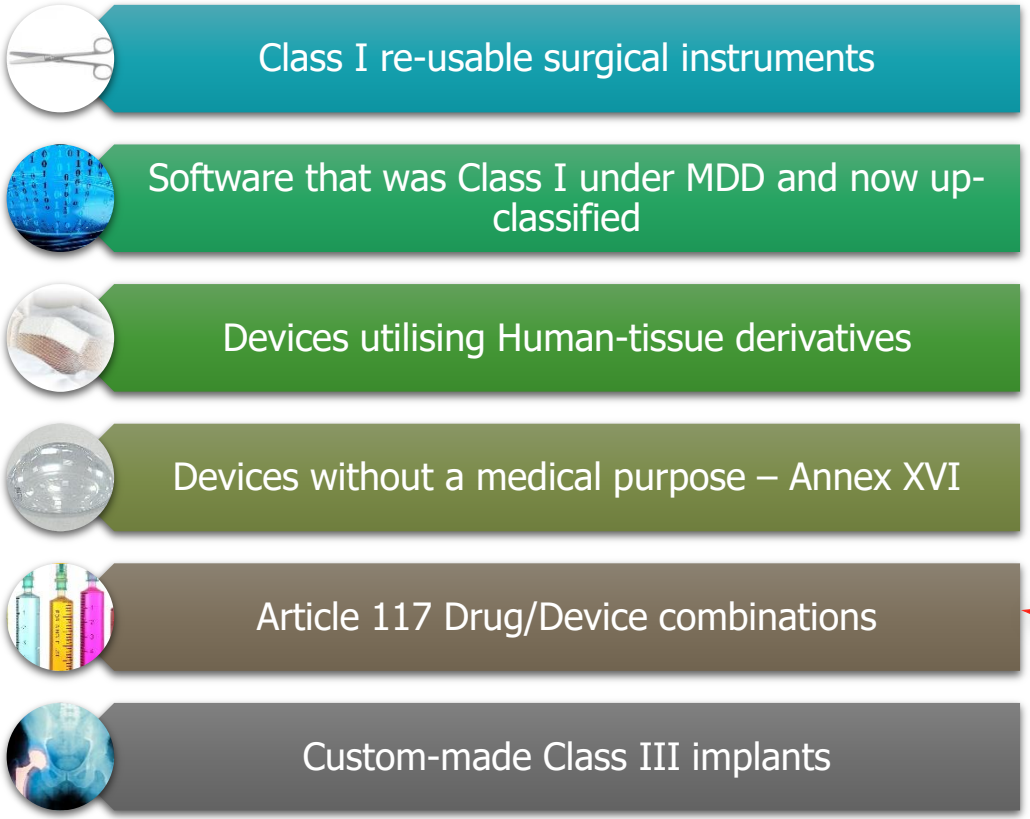


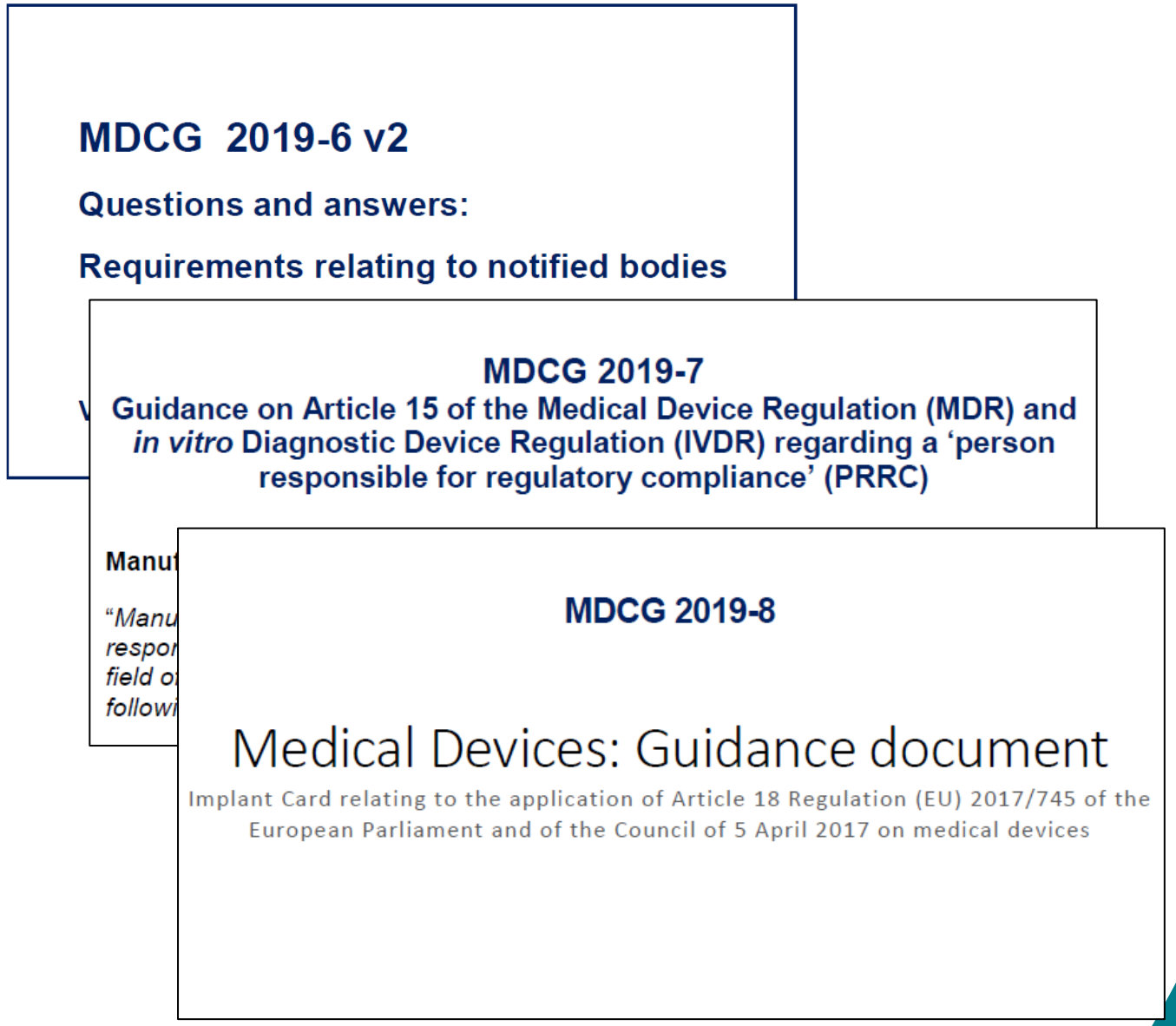
So the Commission has been very busy…

MDCG
7 documents on various topics since June 2019

SCHEER guidelines on Phthalates

EMA Q&A on Article 117

Many other draft guidance documents from various WGs – CIE, NET, Classification, Borderline



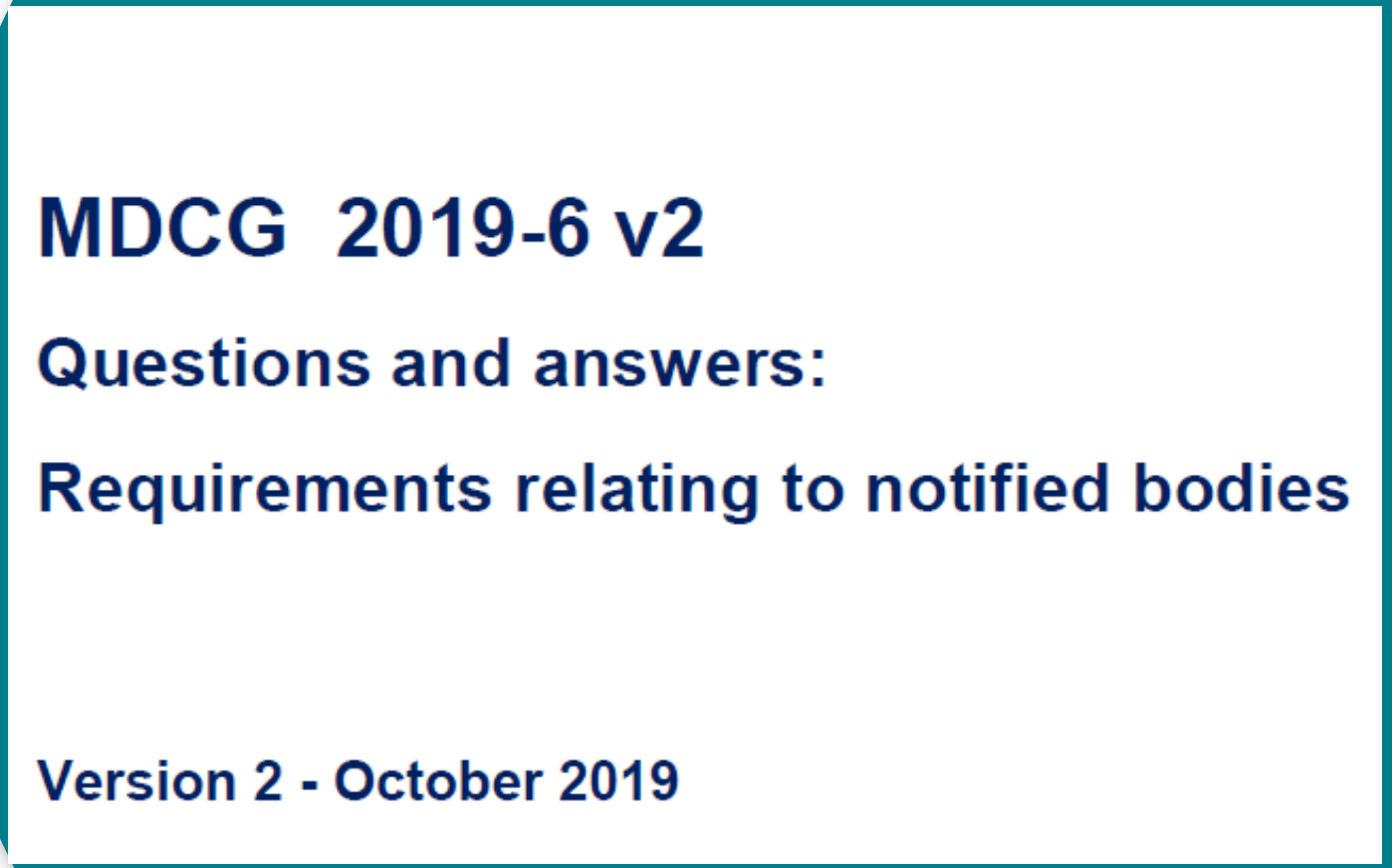
*Source - https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

MDCG Documents

Published by Commission; https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

Legally non-binding; but State of art; To ensure uniform application of provisions within MDR/IVDR

Requirements related to notified bodies
(but also important for Manufacturers)



MDCG 2019-6 V2

I.6. May CAB provide pre-certification services?

Pre-certification services are not allowed before an application is lodged by the manufacturer (e.g. review of clinical data or assessment of the quality management system aside from regulatory standards such as ISO 13485) and therefore these services have to take place under the scope of the application.

No pre-certification activities allowed under MDR/IVDR

IV.1. Do devices certified under the Directives need to be subject to a full conformity assessment under the new Regulations if the manufacturer applies for certification under the MDR / IVDR?

The conformity assessment activities described under Article 52 / Article 48 apply to any certificate issued under the new regulations. As no exceptions were established under the regulations for the migration or transfer of MDD/AIMDD/IVDD certificates to the MDR / IVDR the general provisions should apply. Therefore, all devices to be certified under the MDR / IVDR should be subject to an initial certification according to the applicable annex. The notified body should ensure that all requirements under the MDR / IVDR are fulfilled. It may not restrict its procedures to gap audits or gap file reviews.

Full assessment under MDR/IVDR even if devices held certificates under Directives

MDCG 2019-6 V2

IV.5. What are the applicable requirements for OBL manufacturers?

The MDR / IVDR does not distinguish between OBL[7] and other manufacturers. There are just "manufacturers" and therefore OBL manufacturers must comply with the legal requirements, as any other manufacturer[8].

Own Brand labellers are treated the same as any other legal manufacturer

IV.2. What should be the criteria for auditing suppliers and subcontractors?

The MDR/IVDR established that the audit of the manufacturer premises must include an audit on the premises of subcontractors and/or suppliers if appropriate. Therefore, the notified body should have criteria for auditing these actors on the basis of their criticality. At the very least, the criteria defined in Section 4.5.2(b) of Annex VII should be applied (i.e. the control over the supplier/subcontractor and its influence on the conformity of the device is essential whereas the sole existence of a certificate against ISO 13485 is not sufficient).

Inadequate supplier controls at legal manufacturer may result in verification audits at suppliers / sub-contractors even if the latter held valid certification

MDCG 2019-6 V2

IV.11. What is the meaning of the last sentence in Section 4.5.1 of Annex VII with regard to the need for notified bodies to take into consideration standards and guidance even if the manufacturer does not claim compliance?

CABs need to consider all the available guidance, common specifications and harmonised standards to carry out its assessments. This means, that CABs will have to consider this documentation when developing its own procedures and processes (including checklists and report templates) and when assessing the manufacturers QMS (e.g. by taking into consideration EN ISO 13485) and technical documentation.

For instance, in order to assess if the solutions adopted by the manufacturer are state of the art and in line with expectations, the CAB need to use the available guidance documents and standards. It should be noted that non-conformities will not be raised against standards or guidance but need to be phrased against legal requirements. For instance, Annex I Chapter I Section 1 of the Regulation which states that "devices shall be safe and effective [...] taking into account the generally acknowledged state of the art" can be used when the technical documentation does not follow standards or guidance.

NBs will consider all available guidance documents, standards etc in their assessments and internal processes when assessing Manufacturers

Person Responsible for Regulatory Compliance

MDCG 2019-7

Guidance on Article 15 of the Medical Device Regulation (MDR) and *in vitro* Diagnostic Device Regulation (IVDR) regarding a 'person responsible for regulatory compliance' (PRRC)

Manufacturers[1] (paragraph 1)

"*Manufacturers shall have available* ***within their organisation*** *at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:*

MDCG 2019-7: Guidance on PRRC (some key points)

Professional experience should be related to EU requirements that apply to medical devices

Organisations with multiple legal entities – Each entity to have its own PRRC

PRRC must be an employee of the organisation

If the legal Manufacturer is based outside EU, the PRRC should be located outside EU.

For legal manufacturers within EU, PRRC should be within EU

The same person cannot be the PRRC for both a manufacturer and their EU authorised representative

SSCP

MDCG 2019-9

Summary of safety and clinical performance

A guide for manufacturers and notified bodies

August 2019

MDCG 2019-9: SSCP – Key Points

- For implantable devices and class III devices, SSCP to have 2 parts – Intended User part and Patient specific part
- SSCPs to be translated into languages accepted in Member states where the device is envisaged to be sold; Translated SSCPs to be available in EUDAMED before a device can be placed on the market in a Member State with specific language requirements
- Class III and IIb implantable non-WET devices – NB to validate all SSCPs at the time of initial assessments
- Class IIa implantable, Class IIb implantable WET devices – NB to validate SSCPs for devices chosen as representative samples at initial certification; Other SSCPs to be uploaded to EUDAMED as unvalidated at the time of initial certification; Unvalidated SSCPs to be validated within the first certification cycle
- Updates to SSCPs may be required through the certificate cycle and at certificate renewals

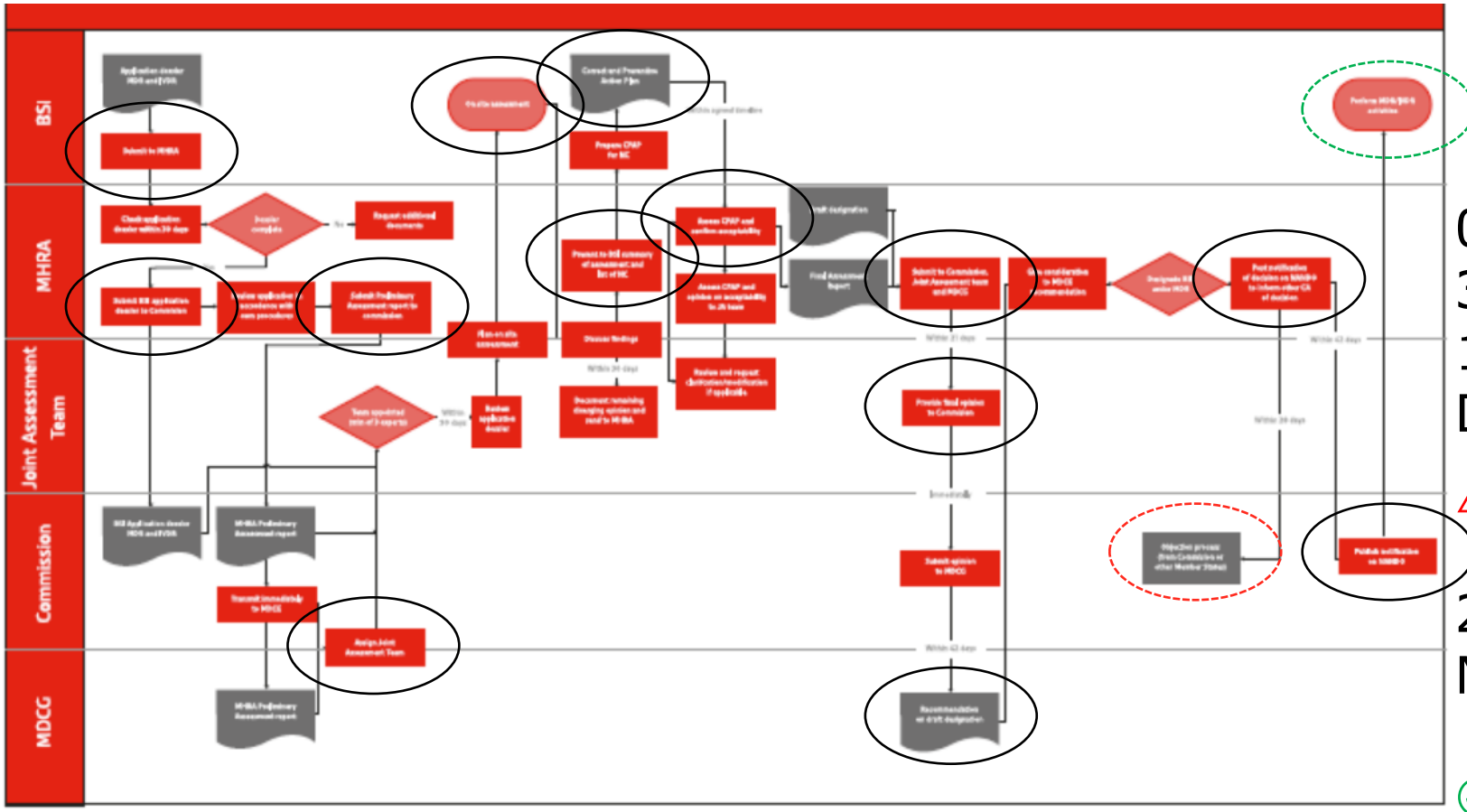
MDR/IVDR

BSI Designation Updates

EU MDR / IVDR – Designation – Article 38-40 / 38-40

MDR:

- 27 Nov 2017
- 14 Dec
- 03 Jan 2018
- 10 Jan
- 09 Apr
- 16 Apr
- 10 May
- 24 Sept
- 17 Oct



07 Nov
30 Nov
19 Dec
Designation

△ **No Objections**

21 Jan 2019
Notification

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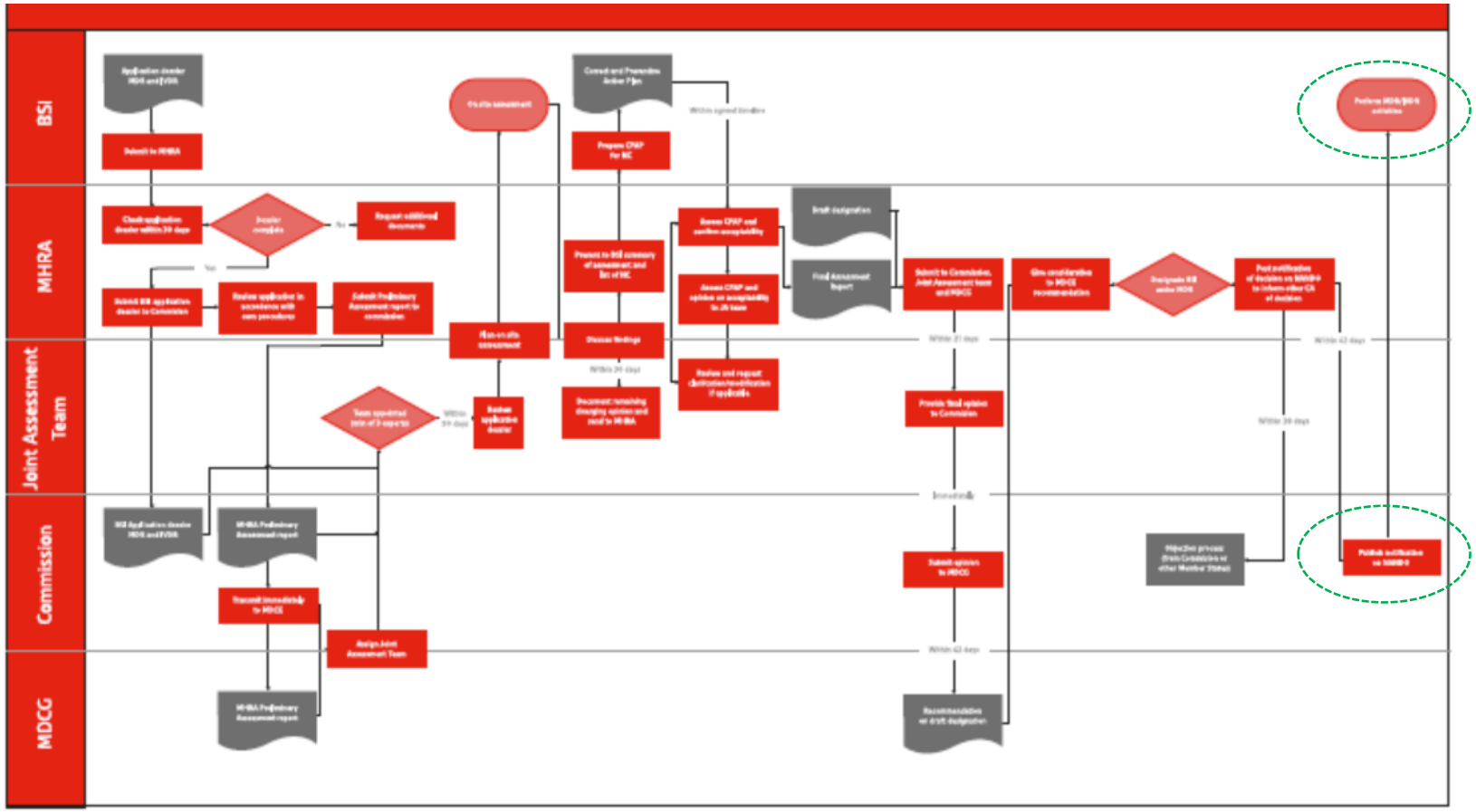
EU MDR / IVDR – Designation – Article 38-40 / 38-40

IVDR:

- 27 Nov 2017
- 15 Dec
- 21 Dec
- 14 May 2018
- 05 Nov
- 08 Nov
- 06 Dec
- 11 Mar 2019



26 Oct 2019
Notification

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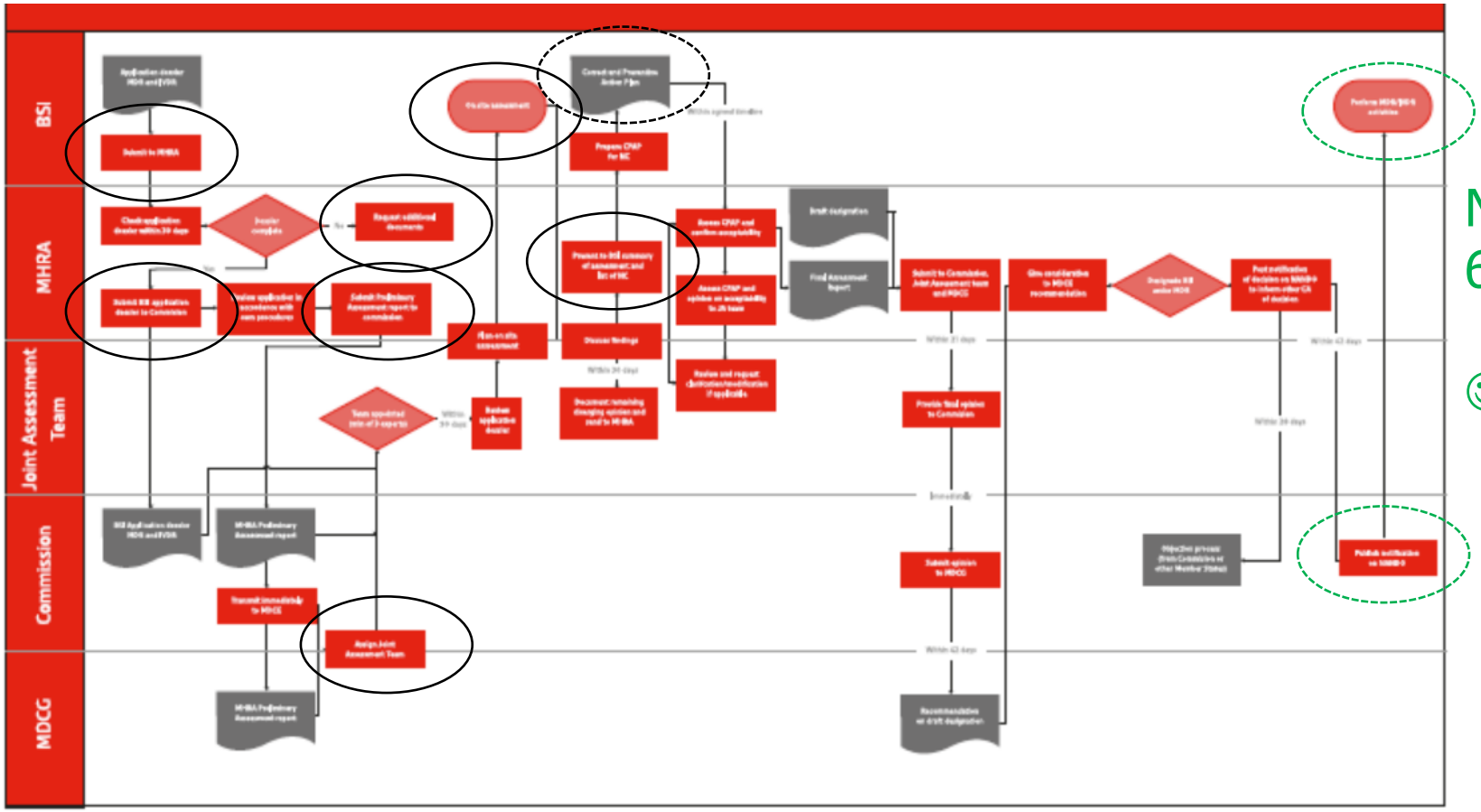
EU MDR / IVDR – Designation – Article 38-40 / 38-40

MDR:
- 27 Nov 2017
- 28 Dec
- 25 Sept 2018
- 26 Sept
- 28 Jan 2019
- 01 Feb

- 22 Feb CAP
- NC Close Out



Notification on 6th Nov 2019

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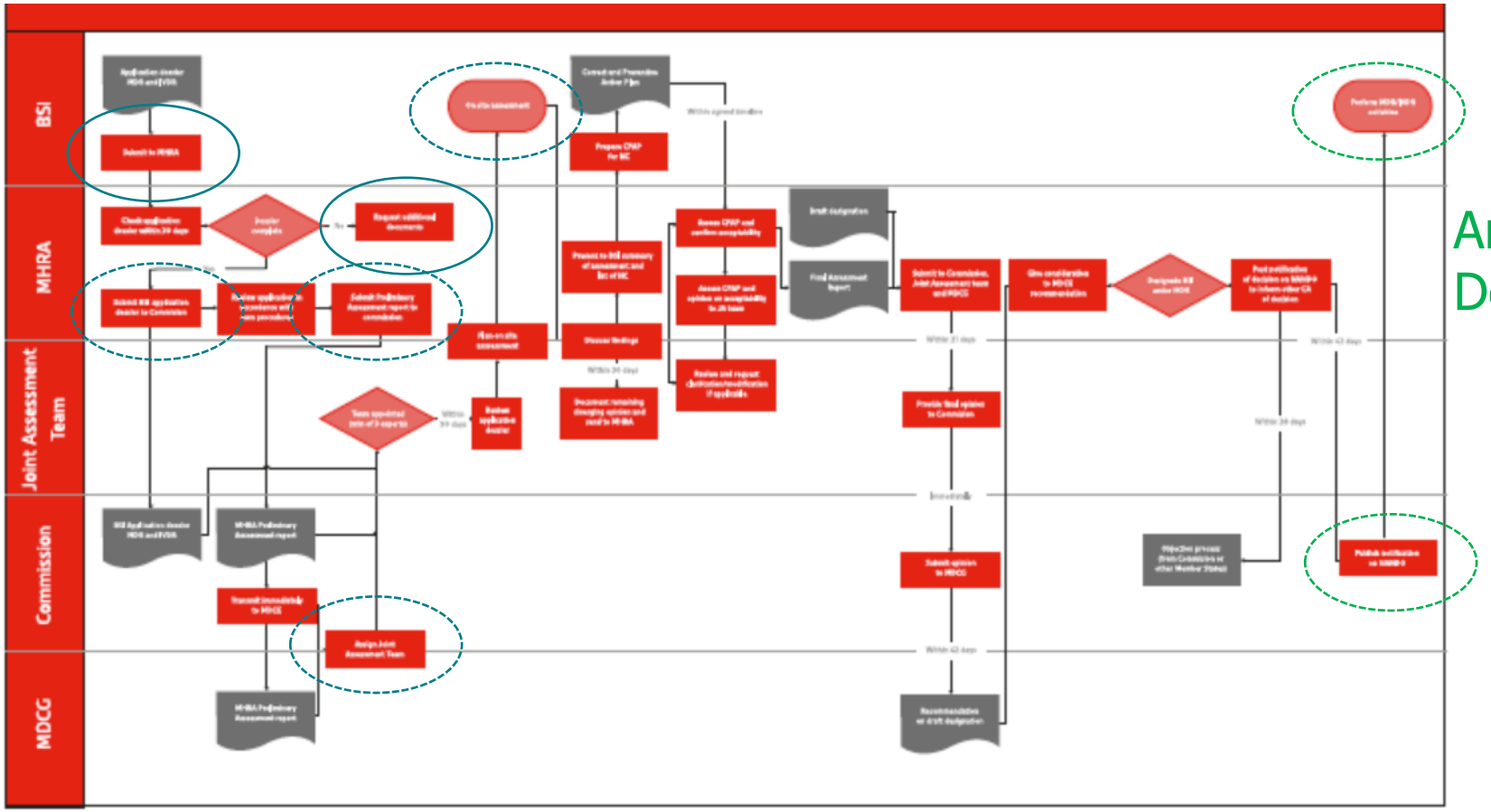
EU MDR / IVDR – Designation – Article 38-40 / 38-40

IVDR:

- 28 Nov 2017
- 28 Dec

- 02 Dec 2018 Everything Submitted

- DG Sante booking
- July 2019



Anticipated Dec 2019

Any questions?