WHEN TRUST MATTERS

Software as medical device under new regulation

25 March 2021

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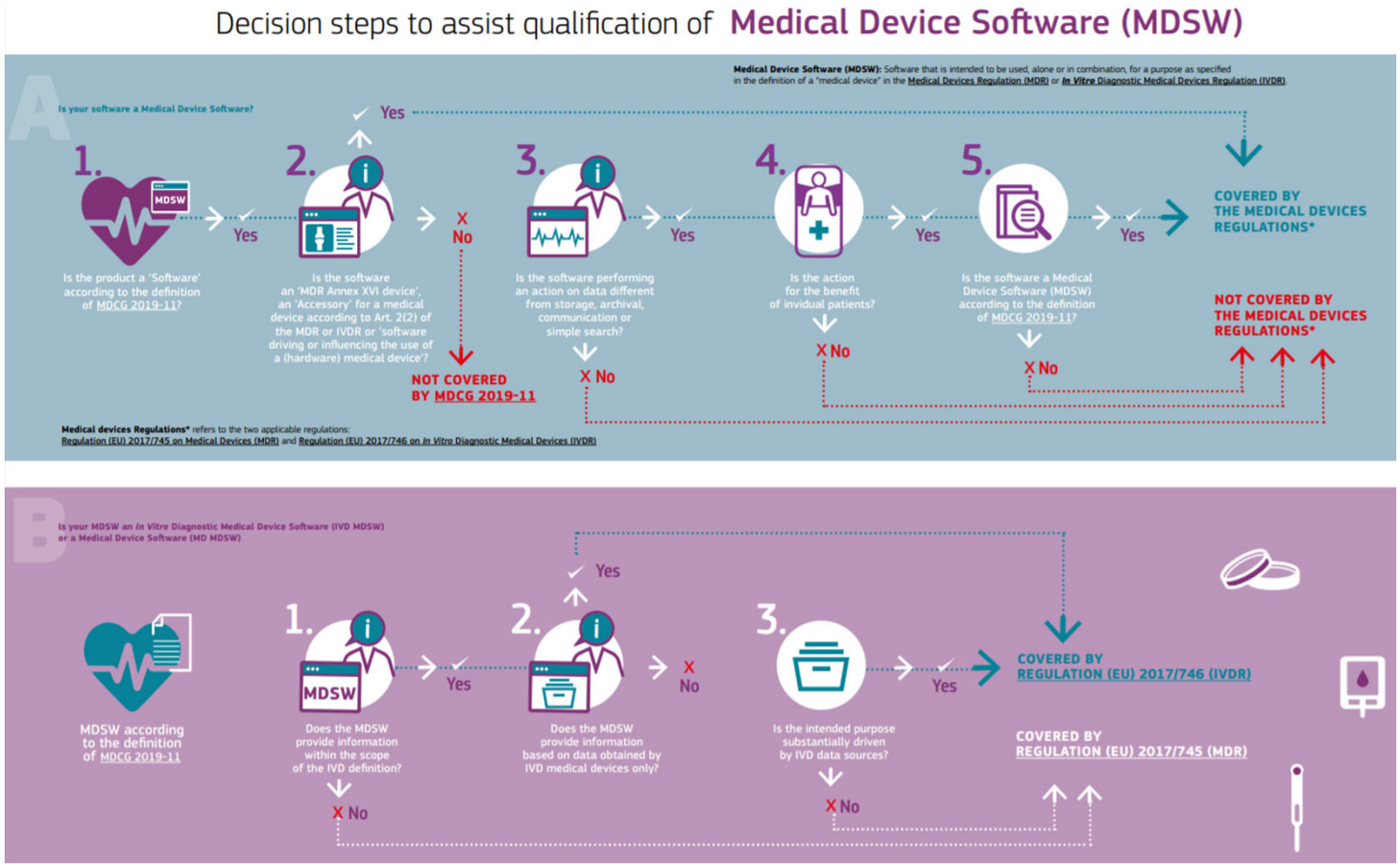
Qualification of software as medical device



https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2021_mdsw_en.pdf

*"Software must have a **medical purpose** on its own to be qualified as a medical devices software (MDSW)"*

"Action on data beyond storage, archival, simple search, communication"

"Computer programs used in healthcare can have applications which consist of both medical device and non-medical device modules"

MDCG 2019-11
https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

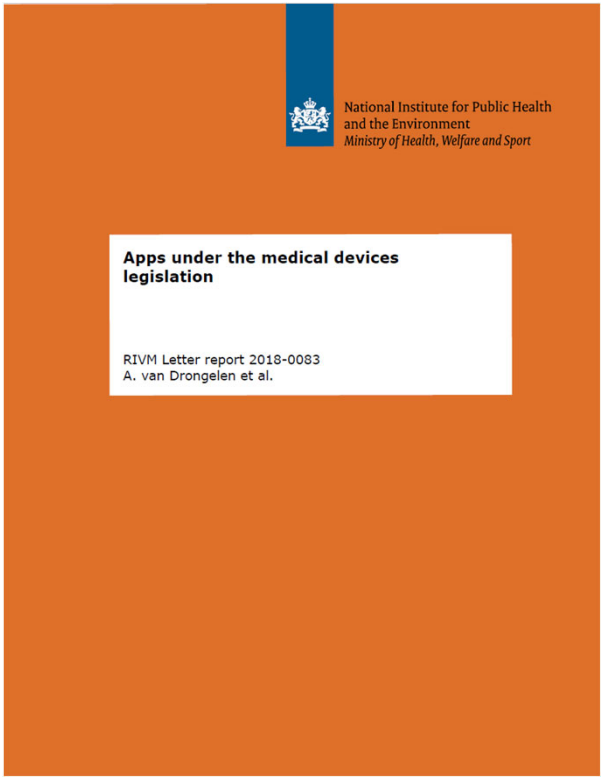
Up-classification of mobile Apps under MDR

Table 3.3.a: Classification of apps according to the MDD

Risk class	N	%
Class I	33	59
Class IIa	16	29
Class IIb	6	11
Class III	1	2
Total	**56**	**100**

Table 3.3.b: Classification of apps according to the MDR

Risk class	N	%
Class I	9	16
Class IIa	35	63
Class IIb	10	18
Class III	2	4
Total	**56**	**100**

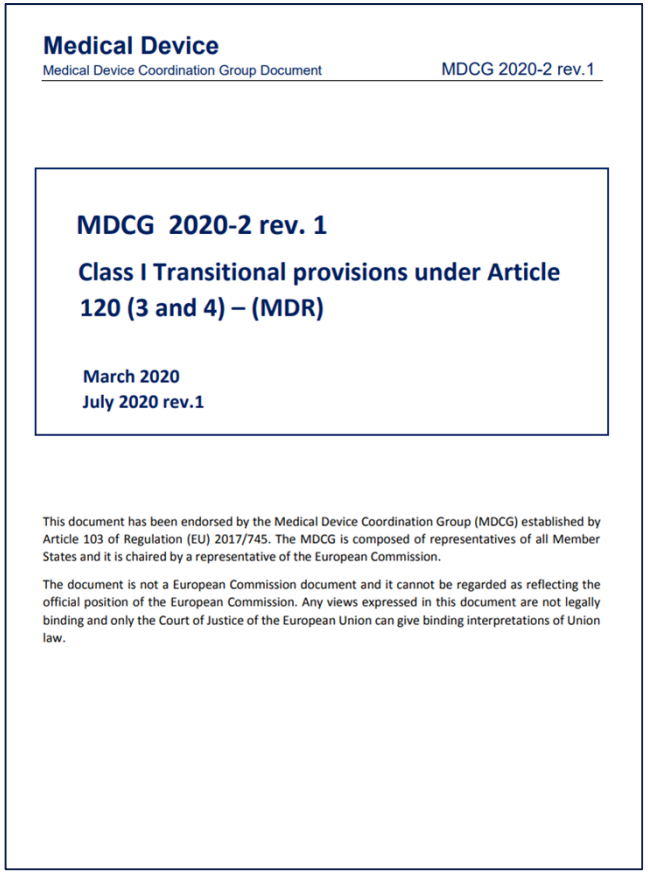


RIVM Letter report 2018-0083 A. van Drongelen et al.

Up-classification and transition

Article 120 Transitional provisions(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 2021 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 2021 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.



Medical Device
Medical Device Coordination Group Document MDCG 2020-2 rev.1

MDCG 2020-2 rev. 1

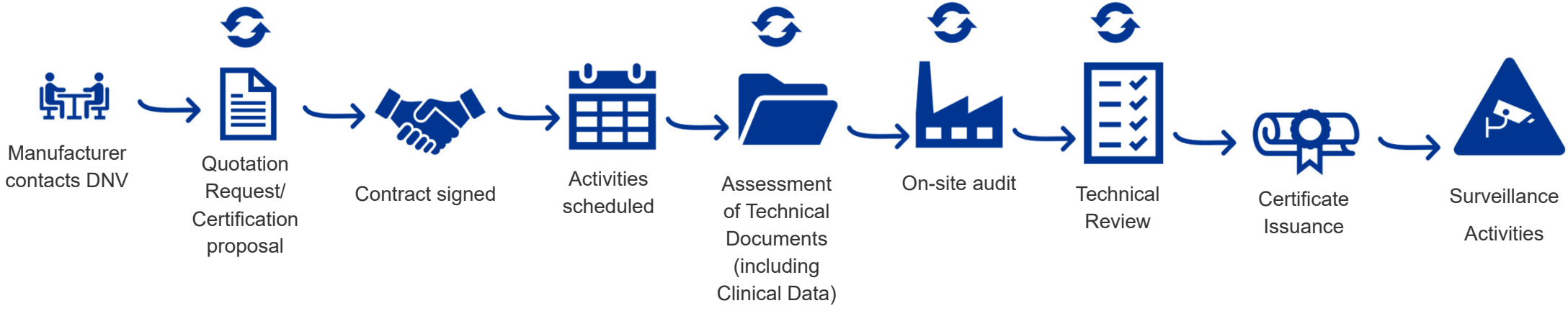
Class I Transitional provisions under Article 120 (3 and 4) – (MDR)

March 2020
July 2020 rev.1

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Certification Process Overview



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Thank you for attention

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