Designation Process of Notified Bodies

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LSA2018 - Lübeck Summer Academy on Medical Technology
Regulatory Affairs
04.07.2018

Content of the presentation

- Designation process under the „old“ system
- Designation process under MDR
  - CAB´s application
  - scope
  - pre-assessment and off-site activities
  - on-site assessment
  - post-assessment activities
  - decision on designation and notification
- Monitoring and surveillance activity
- Re-assessment

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View back to MDD/AIMDD/IVDD

Requirements for a notified body for designation and scope-extension

- Directives 93/42/EEC (MDD), 90/385/EEC (AIMDD) and 98/79/EC IVDD
- Commission implementing regulation (EU) no. 920/2013 (excl. IVDD)
- **national law** Medical Devices Act (MPG) § 15 to § 18
- **national rules** and documents from the national designation authority (EK-Med)

Best practice Guide NBOG 2016-1

„old“ system

12 pages

(Re-)designation of notified bodies: Process for joint assessments

1 Scope

1.1 This guide is intended to provide guidance to designating authorities (DAs) and joint assessment teams (JATs) when conducting (re-)designation and scope extension assessments of notified bodies (NBs) under Commission Implementing Regulation (EU) No 920/2013 (hereafter referred to as the Regulation). As the majority of those assessments will be for re-designations the timelines defined below refer primarily to those.

1.2 Whilst the Regulation does not apply to Directive 98/79/EC (IVDD), it could be the case that an NB wishes to combine its (re-)designation under both Council Directive 90/385/EEC on active implantable medical devices (AIMDD) and Council Directive 93/42/EEC on medical devices (MDD) with the IVDD. In such a case the joint assessment process deals solely with the MDD / AIMDD. Nevertheless, as the prerequisites for designation under both of those Directives have a bearing on an NB's capability to perform conformity assessments according to the IVDD, DAs shall consider the outcome of the joint assessment on the MDD / AIMDD when deciding on an NB's fitness to operate under the IVDD.

2 Pre-assessment activities

2.1 **NB's application**: When applying for (re-)designation, or for an extension of its scope of designation, the (applicant) NB shall use the application form NBOG F 2014-1 set out in

Regulation „old“ and „new“

Directive 93/42/EEC Art. 16 + Annex XI → **4 pages**
MPG third chapter → **6 pages**
Regulation (EU) No. 920/2013 → **12 pages**
10 Articel, 2 Annexes

factor 5 !

MDR (EU) 2017/745
chapter IV 16 articles → **25 pages**

Annex VII and additional requirements in Annex IX – XI
→ **43 pages**

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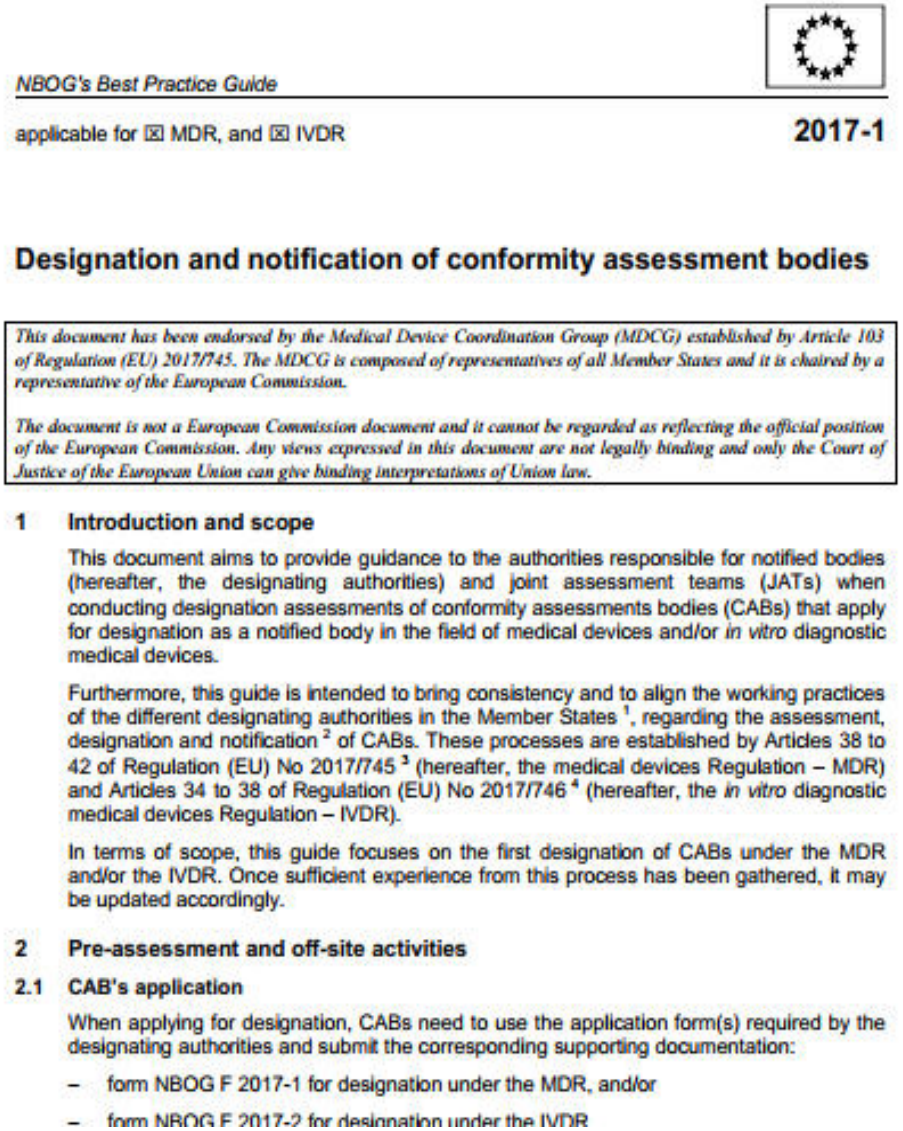
Best practice Guide New Process

16 pages



NBOG's Best Practice Guide

applicable for ☒ MDR, and ☒ IVDR

2017-1

Designation and notification of conformity assessment bodies

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.

1 Introduction and scope

This document aims to provide guidance to the authorities responsible for notified bodies (hereafter, the designating authorities) and joint assessment teams (JATs) when conducting designation assessments of conformity assessments bodies (CABs) that apply for designation as a notified body in the field of medical devices and/or *in vitro* diagnostic medical devices.

Furthermore, this guide is intended to bring consistency and to align the working practices of the different designating authorities in the Member States [1], regarding the assessment, designation and notification [2] of CABs. These processes are established by Articles 38 to 42 of Regulation (EU) No 2017/745 [3] (hereafter, the medical devices Regulation – MDR) and Articles 34 to 38 of Regulation (EU) No 2017/746 [4] (hereafter, the *in vitro* diagnostic medical devices Regulation – IVDR).

In terms of scope, this guide focuses on the first designation of CABs under the MDR and/or the IVDR. Once sufficient experience from this process has been gathered, it may be updated accordingly.

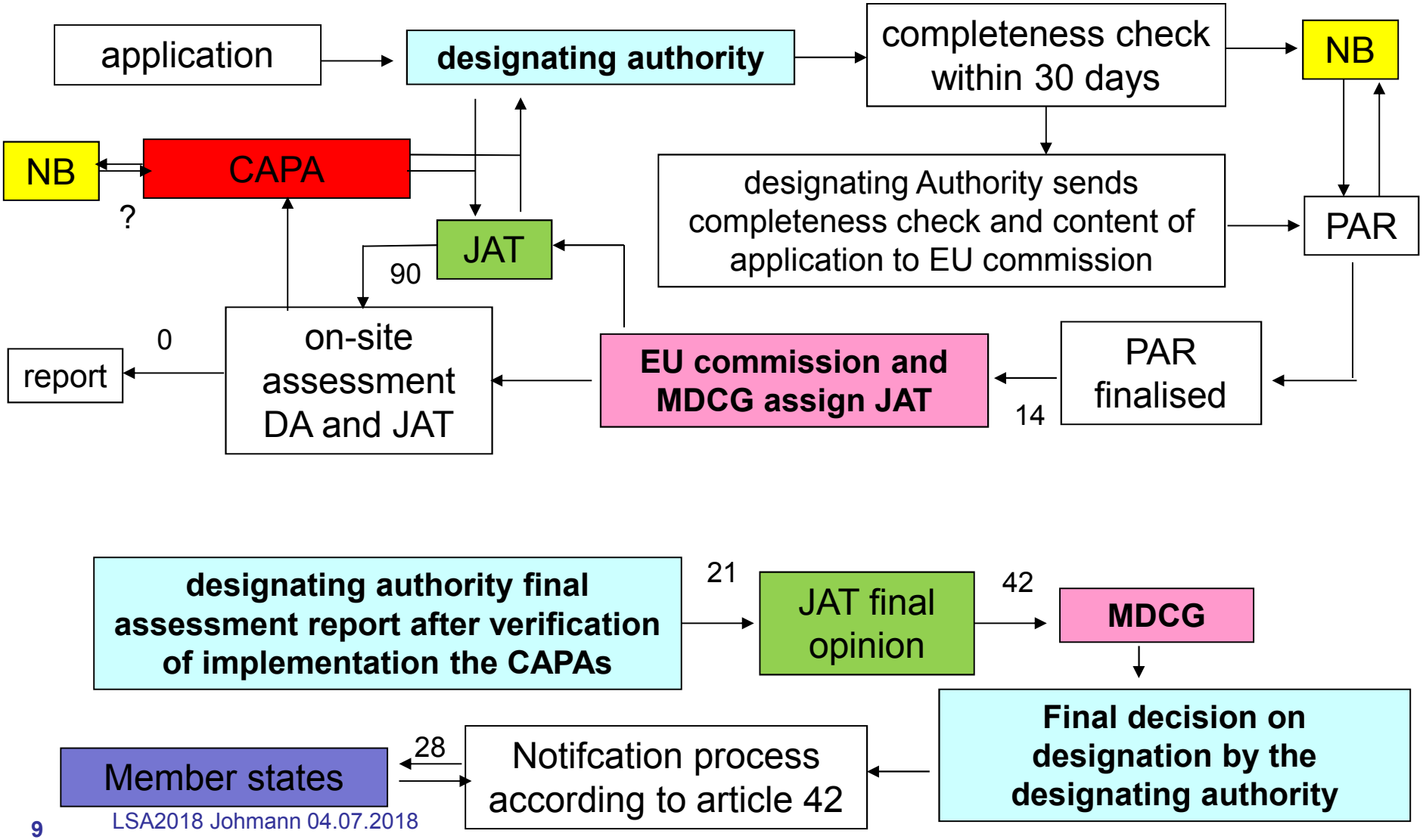
2 Pre-assessment and off-site activities

2.1 CAB's application

When applying for designation, CABs need to use the application form(s) required by the designating authorities and submit the corresponding supporting documentation:

- form NBOG F 2017-1 for designation under the MDR, and/or
- form NBOG F 2017-2 for designation under the IVDR

Designation Process „new“



Who can submit an application?

- every legal entity?
- according to my personal understanding only conformity assessment bodies (CAB) can submit an application

Article 38 (1) MDR:
conformity assessment bodies shall submit an application

Article 2 Definitions:
(41) „conformity assessment body“ means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection

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  - on-site assessment
  - post-assessment activities (CAPA)
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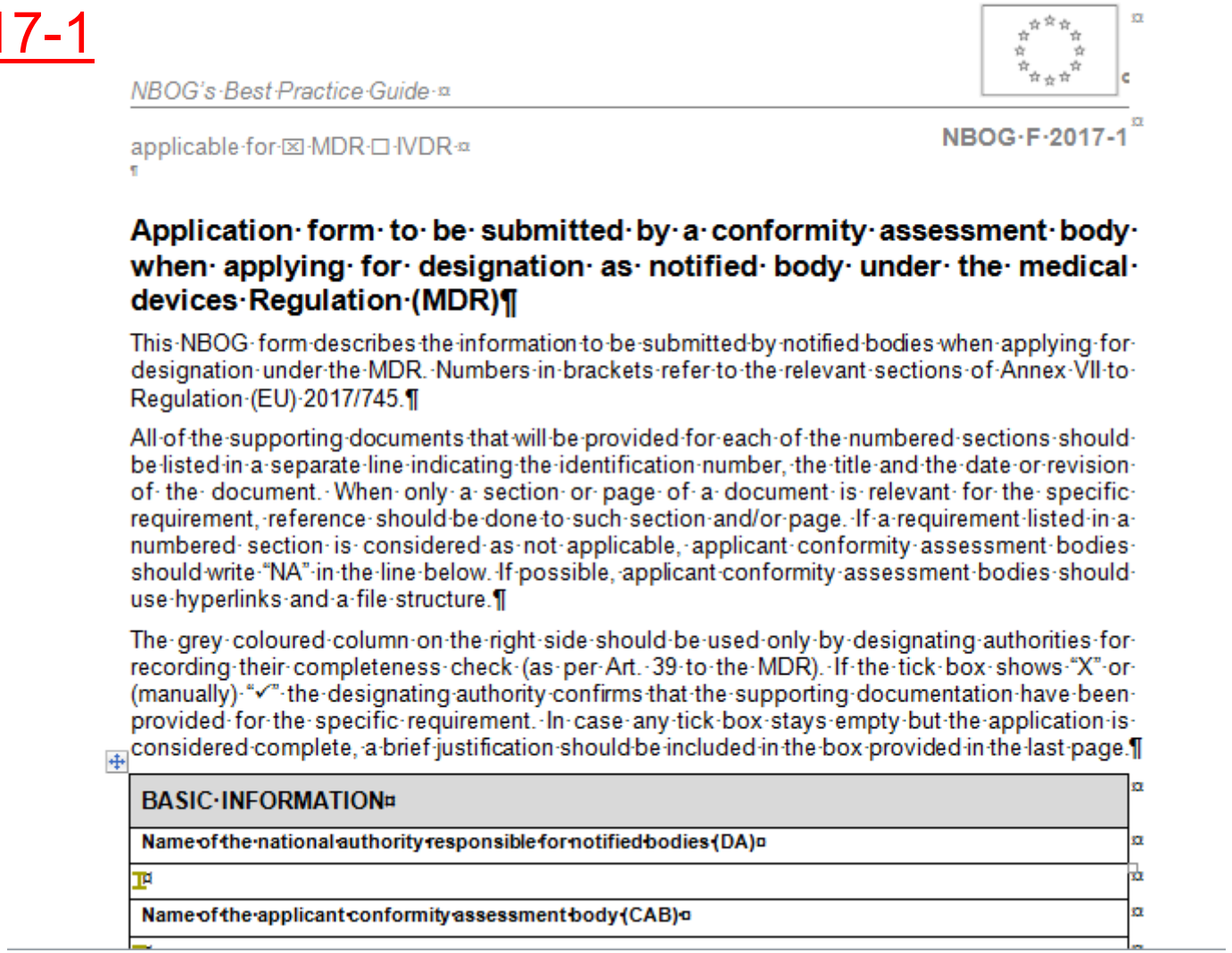
Scope for MDR – application form

NBOG F 2017-1



NBOG's Best Practice Guide

applicable for ☒ MDR ☐ IVDR

NBOG F 2017-1

Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices Regulation (MDR)

This NBOG form describes the information to be submitted by notified bodies when applying for designation under the MDR. Numbers in brackets refer to the relevant sections of Annex VII to Regulation (EU) 2017/745.

All of the supporting documents that will be provided for each of the numbered sections should be listed in a separate line indicating the identification number, the title and the date or revision of the document. When only a section or page of a document is relevant for the specific requirement, reference should be done to such section and/or page. If a requirement listed in a numbered section is considered as not applicable, applicant conformity assessment bodies should write "NA" in the line below. If possible, applicant conformity assessment bodies should use hyperlinks and a file structure.

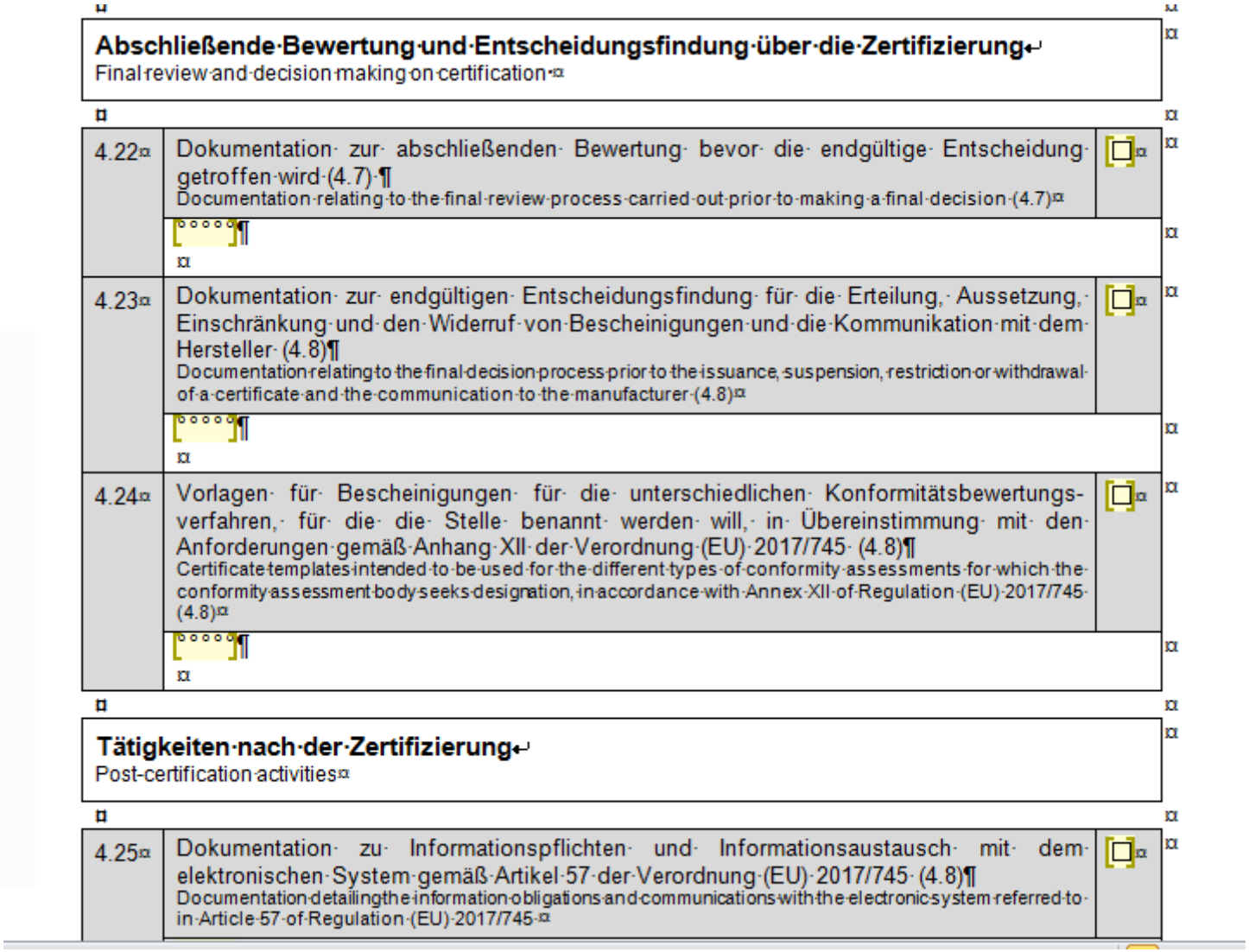
The grey coloured column on the right side should be used only by designating authorities for recording their completeness check (as per Art. 39 to the MDR). If the tick box shows "X" or (manually) "✓" the designating authority confirms that the supporting documentation have been provided for the specific requirement. In case any tick box stays empty but the application is considered complete, a brief justification should be included in the box provided in the last page.

BASIC INFORMATION
Name of the national authority responsible for notified bodies (DA)
Name of the applicant conformity assessment body (CAB)

Supporting documentation

application form

- 03.12
- 03.13
- 03.14
- 03.15
- 04.01
- 04.02
- 04.03
- 04.04
- 04.05
- 04.06
- 04.07
- 04.08
- 04.09
- 04.10
- 04.11



Abschließende Bewertung und Entscheidungsfindung über die Zertifizierung
Final review and decision making on certification

4.22	Dokumentation zur abschließenden Bewertung bevor die endgültige Entscheidung getroffen wird (4.7) Documentation relating to the final review process carried out prior to making a final decision (4.7)	☐
4.23	Dokumentation zur endgültigen Entscheidungsfindung für die Erteilung, Aussetzung, Einschränkung und den Widerruf von Bescheinigungen und die Kommunikation mit dem Hersteller (4.8) Documentation relating to the final decision process prior to the issuance, suspension, restriction or withdrawal of a certificate and the communication to the manufacturer (4.8)	☐
4.24	Vorlagen für Bescheinigungen für die unterschiedlichen Konformitätsbewertungs-verfahren, für die die Stelle benannt werden will, in Übereinstimmung mit den Anforderungen gemäß Anhang XII der Verordnung (EU) 2017/745 (4.8) Certificate templates intended to be used for the different types of conformity assessments for which the conformity assessment body seeks designation, in accordance with Annex XII of Regulation (EU) 2017/745 (4.8)	☐

Tätigkeiten nach der Zertifizierung
Post-certification activities

4.25	Dokumentation zu Informationspflichten und Informationsaustausch mit dem elektronischen System gemäß Artikel 57 der Verordnung (EU) 2017/745 (4.8) Documentation detailing the information obligations and communications with the electronic system referred to in Article 57 of Regulation (EU) 2017/745	☐

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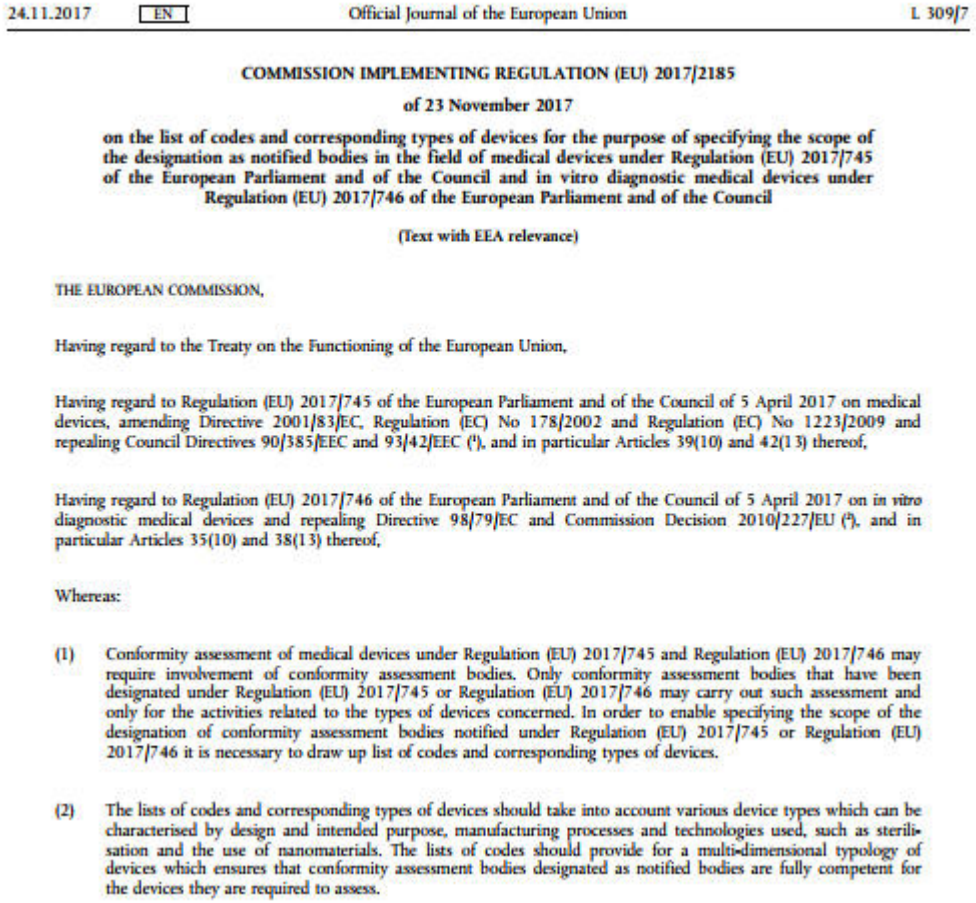
Scope for application MDR

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185
23 November 2017
the list of codes



24.11.2017 EN Official Journal of the European Union L 309/7

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185

of 23 November 2017

on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (1), and in particular Articles 39(10) and 42(13) thereof,

Having regard to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (2), and in particular Articles 35(10) and 38(13) thereof,

Whereas:

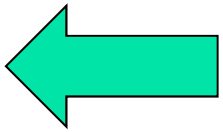
(1) Conformity assessment of medical devices under Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated under Regulation (EU) 2017/745 or Regulation (EU) 2017/746 may carry out such assessment and only for the activities related to the types of devices concerned. In order to enable specifying the scope of the designation of conformity assessment bodies notified under Regulation (EU) 2017/745 or Regulation (EU) 2017/746 it is necessary to draw up list of codes and corresponding types of devices.

(2) The lists of codes and corresponding types of devices should take into account various device types which can be characterised by design and intended purpose, manufacturing processes and technologies used, such as sterilisation and the use of nanomaterials. The lists of codes should provide for a multi-dimensional typology of devices which ensures that conformity assessment bodies designated as notified bodies are fully competent for the devices they are required to assess.

Scope of application „old“ /“new“

codes reflecting the design and intended purpose of the device

- MDD + AIMDD — 43 codes
10 horizontal codes
- MDR — 44 codes
27 horizontal codes
- IVDD — 22 codes
6 horizontal codes
- IVDR — 33 codes
47 horizonal codes



IVDR horizontal codes Annex II 2017/2185

- IVS-code: IVD with specific characteristics (instruments, software, self testing) (10)
- IVT-code: IVD for which specific technologies are used (11)
- IVP-code: IVD which require specific knowledge in examination procedures for purpose of product verification (14)
- IVD-code: IVD specific knowledge in laboratory and clinical disciplines (12)

Conformity assessment procedures

- in the application the CAB has to select the different conformity assessment procedures → see Article 52 MDR (depending on the classification of the medical device)
- Annex VII MDR: **no conformity assessment procedures for**
  - Article 16 importers, distributors or other persons → repacking → certificate for QM issued by a NB
  - Article 17 single-use devices reprocessing → compliance with CS certified by a NB

Scope for MDR (DA website)

MDA·CODE	Aktive·nichtimplantierbare·Produkte·für·bildgebende·Verfahren,·zur·Überwachung·und/oder·Diagnose Active·non-implantable·devices·for·imaging,·monitoring·and·/·or·diagnosis	Anhänge Annexes					Bedingungen Conditions
		IX(I)	IX(II)	X	XI(A)	XI(B)	
MDA·0201	Aktive·nichtimplantierbare·Produkte·für·bildgebende·Verfahren·mit·ionisierenden·Strahlen Active·non-implantable·imaging·devices·utilising·ionizing·radiation	☐	☐	☐	☐	☐	·····
MDA·0202	Aktive·nichtimplantierbare·Produkte·für·bildgebende·Verfahren·mit·nicht-ionisierenden·Strahlen Active·non-implantable·imaging·devices·utilising·non-ionizing·radiation	☐	☐	☐	☐	☐	·····
MDA·0203	Aktive·nicht·implantierbare·Produkte·zur·Überwachung·von·vitalen·physiologischen·Parametern Active·non-implantable·devices·for·monitoring·of·vital·physiological·parameters	☐	☐	☐	☐	☐	·····
MDA·0204	Sonstige·aktive·nichtimplantierbare·Produkte·zur·Überwachung·und/oder·Diagnose Other·active·non-implantable·devices·for·monitoring·and·/·or·diagnosis	☐	☐	☐	☐	☐	·····

MDA·CODE	Aktive·nichtimplantierbare·therapeutische·Produkte·und·allgemeine·aktive·nichtimplantierbare·Produkte Active·non-implantable·therapeutic·devices·and·general·active·non-implantable·devices	Anhänge Annexes					Bedingungen Conditions
		IX(I)	IX(II)	X	XI(A)	XI(B)	
MDA·0301	Aktive·nichtimplantierbare·Produkte·mit·ionisierenden·Strahlen Active·non-implantable·devices·utilising·ionizing·radiation	☐	☐	☐	☐	☐	·····
MDA·0302	Aktive·nichtimplantierbare·Produkte·mit·nicht-ionisierenden·Strahlen Active·non-implantable·devices·utilising·non-ionizing·radiation	☐	☐	☐	☐	☐	·····

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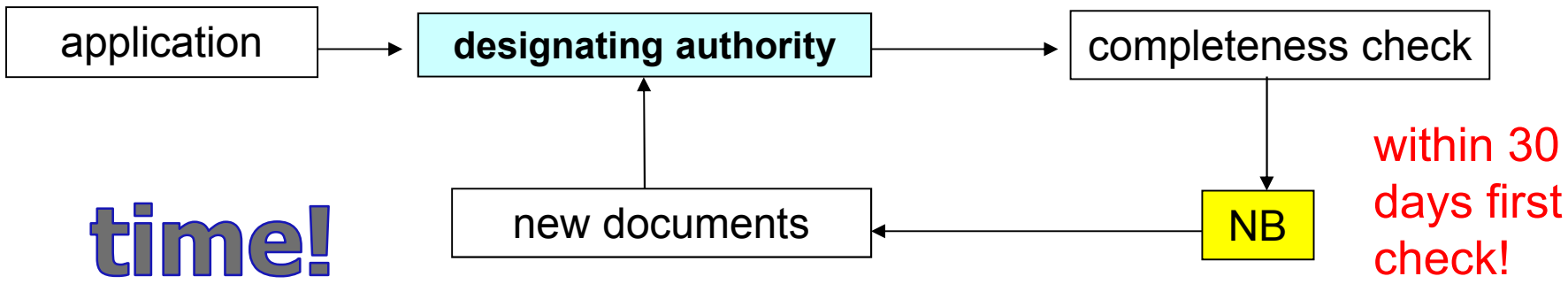
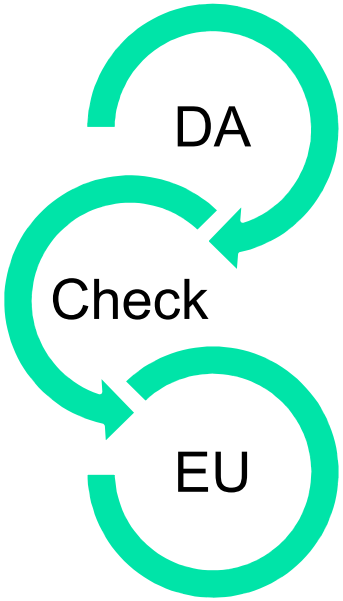
Designation Process „new“- application



- Designating authority will perform an initial review of the application to verify the completeness of the designation application form and supporting documentation (Annex VII MDR) within 30 days
- any delays in the initial completeness check review phase due to missing information may result in subsequent delays in the overall designation process!

Application review

- once the application is considered complete, the DA must submit the completeness check to the European Commission



Best practice Guide - PAR

NBOG's Best Practice Guide

applicable for ☒ MDR ☐ IVDR

NBOG-F-2017-5

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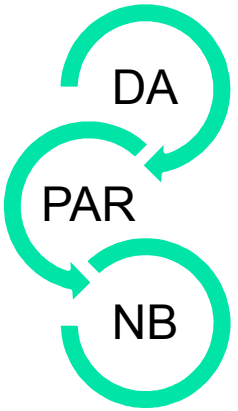
Preliminary assessment review template

DETAILS ON THE APPLICATION AND THE REVIEWERS	
Name and (if applicable) identification number of Conformity Assessment Body (CAB)	
Name of Designating Authority (DA)	
Project number(s) of DA	

PAR outcome of the review

- yes
- yes, with issues described .. to be clarified during the onsite assessment
- no, the deficiencies described below have to be clarified before an onsite assessment
- no



PAR preliminary assessment report

- There is no legislative timeframe for completion for the preliminary assessment report (PAR see NBOG F 2017-5)
- This detailed assessment could take between 3 and 8 weeks upon finalisation of the completeness check.
- Outcome of the review of the application will be used as a base for the on-site assessment.

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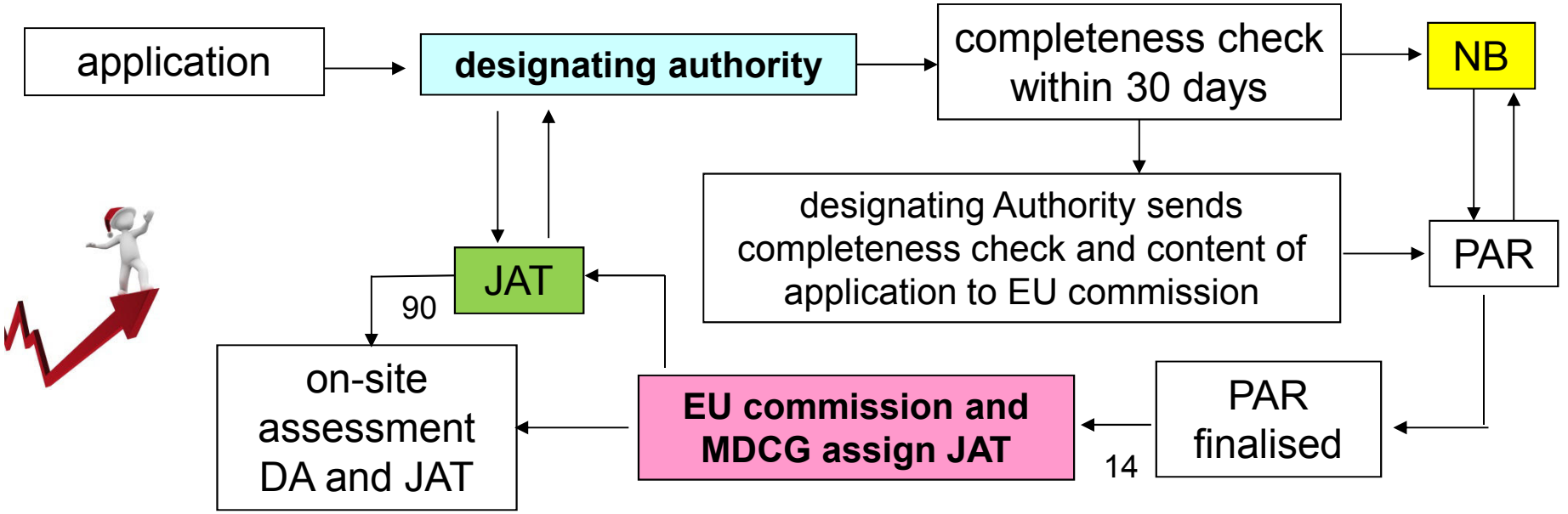
Assessment of the application by the JAT



- DA submit the preliminary assessment report to SANTE/F
- appointment of the JAT and scheduling of the on-site assessment, announcement of the on-site assessment
- assessment of the application by the JAT
- coordination between DA and the JAT

On-site assessment under MDR

- assessmentplan (NBOG document ?)
- EU Joint Assessment Team (JAT) one expert from the European Commission and two experts from a pool of national experts selected from European designating authorities (see Article 40)

capacity of the NB meeting-rooms

Documents: machine translation

national experts different experience

language of the assessment!

On-site assessment under MDR

- the on-site assessment will cover all of the designation requirements laid down in the MDR
- for four to five days depends of the scope!
- the assessment shall be led by the DA responsible for notified bodies
- CAB has sufficient personnel to clarify the questions from each member of the overall assessment team

availability of personnel

On-site-assessment one week

Compliance with Annex VII MDR

- **Organisation and general requirements**

Reporting lines, shareholder, subsidiaries, legal and operational relationships

- **Independence, impartiality, confidentiality …**

Independence from manufacturer, no consulting activities, employee without any conflict of interest

- **Quality Management Requirements**

Compliance with Annex VII MDR

- **Ressource requirements**

Qualification criteria in relation to personnel, documentation of qualification, training, authorisation of personnel, subcontractors, external experts

real personal-files

- **Process requirements**

Quotation, pre-application activities, application review, contract, allocation of resouces, conformity assessment activities, reporting, final reviews, decision, certification, surveillance, post-certification monitoring, re-certification

mock-up-files

Best practice Guide – 2017-2 Personnel

NBOG's Best Practice Guide

applicable for ☒ MDR, and ☒ IVDR

2017-2

Guidance on the Information Required for Conformity assessment bodies' Personnel Involved in Conformity Assessment Activities

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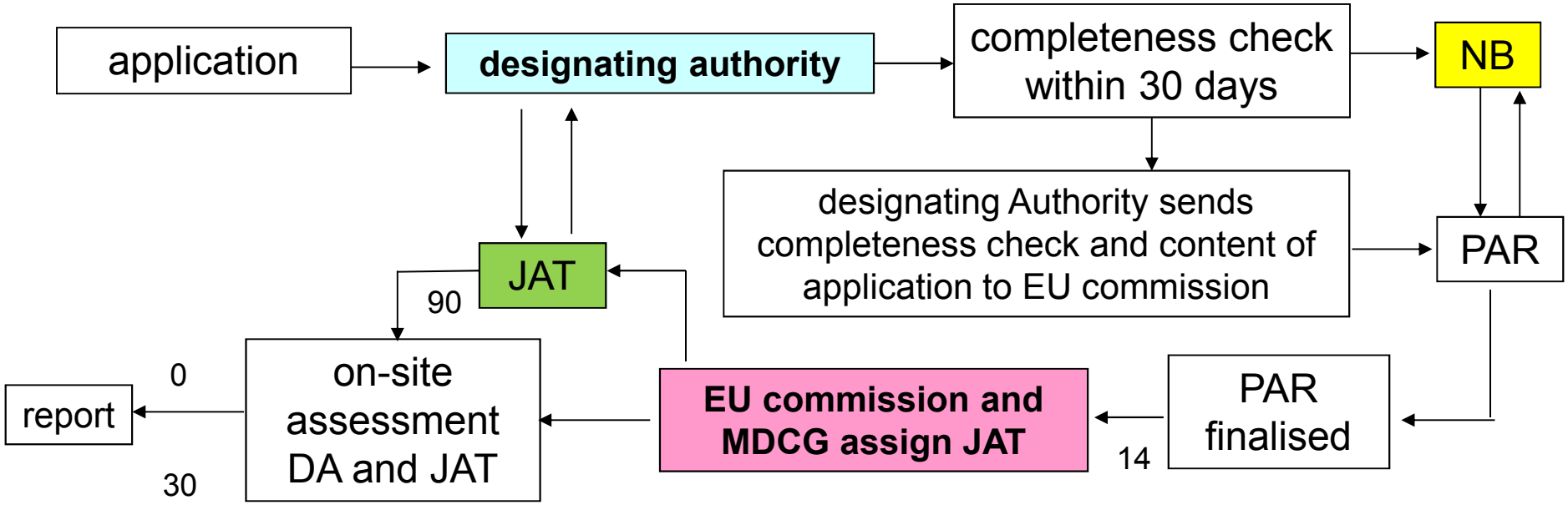
1. Introduction

The Regulations (Regulation (EU) 2017/745 on medical devices (hereafter MDR) and Regulation (EU) 2017/746on *in vitro* diagnostic medical devices (hereafter IVDR)) require that conformity assessment bodies (CABs) have the necessary personnel and have access to all competence needed to perform properly the technical, scientific and administrative tasks entailed in the conformity assessment activities and for the type of devices in relation to which they are designated.

To ensure consistency and transparency, the CAB will have a procedure(s) in place to ensure that the selection, training and authorisation of personnel are fully documented. The

On-site assessment



- list of non-compliances
- Closing meeting
- existence of different interpretations of the legal requirements by DA and the JAT → diverging opinions

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Post-assessment activities

- post-assessment → 30 days the JAT-coordinator (agreement with the rest of the JAT team) issue remaining diverging opinions → DA

→ 20 days DA comments to the JAT

CAPA

- The confirmed CAPA plan and the designating authority's opinion thereon will be forwarded by the designating authority to SANTE/F.
- **JAT review the CAPA plan**
- DA finalise its assessment of the CAPA plan and provide the CAB with feedback.
- Final review of the implementation of the CAPA plan to address the non-compliances prior to designation decision

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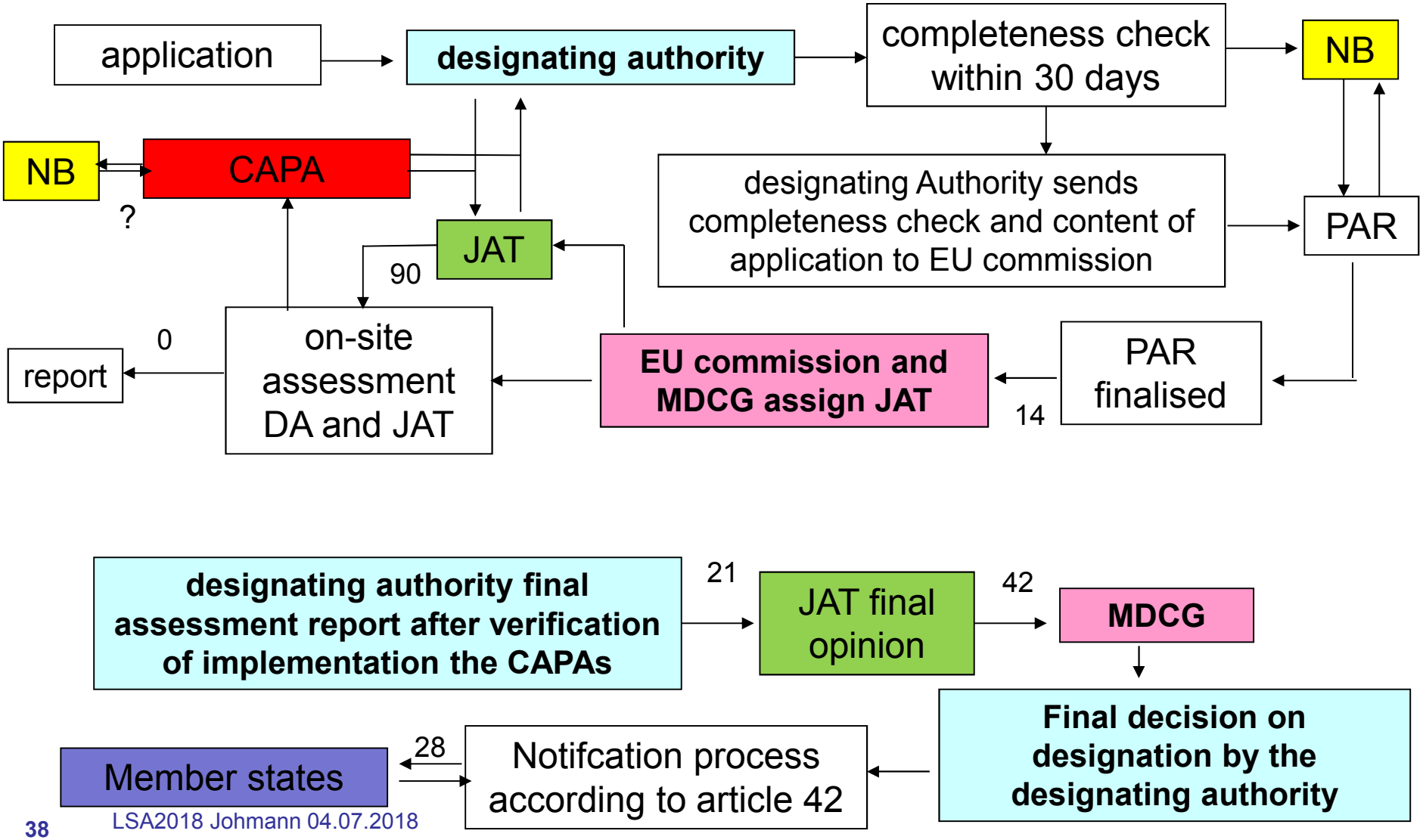
Designation Process „MDR/IVDR“



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Surveillance activity DA

Regular monitoring

- at least once a year → surveillance assessment (including subsidiaries and subcontractors) on-site
- observed audits
- review the assessments by NB of manufacturers´ technical documentation, in particular clinical evaluatiion documentation

For special causes

- unannounced assessment

The DA shall submit its annual plan to MDCG and to the Commission.

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Re-assessment of NB

- 3 years after notification of a NB

  later again every fourth year

  complete re-assessment with JAT

- same process for extensions of the scope of the designation (extension = one horizontal code?)

Questions????

Manufacturer/ companies

- will my notified body be new-designated under MDR?
- when will that be?
- when can my product-files be assessed?

Notified bodies

- How fast can the designation happen?
- Designation may take 18 months

Application from manufacturer, when?

Certification start when the designation process is finished

Not before!

Requirement in Annex VII MDR section 4.3 „Application review and contract“: ..the ability of the notified body to assess the application **based on its designation …**

Thank you for your attention!

Dr Andrea Johmann