MDCG 2022-13
Designation, re-assessment and notification of conformity assessment bodies and notified bodies

August 2022

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.

Contents

1 Introduction and scope

This document[1] aims to provide guidance to the authorities responsible for notified bodies (hereafter, the Designating Authorities) and joint assessment teams (JATs) when conducting:

i. assessments of conformity assessments bodies (CABs) that apply for designation as a notified body (NB) in the field of medical devices and/or in vitro diagnostic medical devices, and

ii. re-assessments of NBs.

Furthermore, this guide is intended to bring consistency and to align the working practices of the different designating authorities in the Member States[2], regarding the assessment, designation, notification and re-assessment of CABs and NBs.

[1] This document was endorsed by MDCG and published as NBOG BPG 2017-1 in its first version in February 2018. Based on experience gained in the context of the joint assessment process, the document has been updated, adding also clarification on the re-assessment process and notification procedure and its revision published as MDCG document.

[2] References made to "Member States" in this guide should be understood as referring to Member States, EEA and EFTA countries and other countries where a relevant agreement covering mutual recognition of designation of CABs

The processes for assessment, designation and notification are established by Articles 38 to 42 of Regulation (EU) 2017/745[3] (hereafter, the Medical Devices Regulation – MDR) and Articles 34 to 38 of Regulation (EU) 2017/746[4] (hereafter, the *in vitro* Diagnostic Medical Devices Regulation – IVDR).

The processes for re-assessment are established by Article 44 (10) of the MDR and Article 40 (10) of the IVDR, whereby it is stated that *three years after notification* of a notified body, and *again every fourth year thereafter*[5], a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VII to MDR and IVDR shall be conducted by the designating authorities and a joint assessment team.

In terms of scope, this guide focuses on the designation of CABs and subsequent re-assessments of NBs under the MDR and/or the IVDR. A subsequent revision will address the processes for changes to designations and notifications (Article 46 MDR and Article 42 IVDR).

Note: In the MDCG, the Commission and Member States have identified notified body capacity as a critical issue and are committed to progress CAB's applications for designation and notification without undue delay.

2 Designation assessments

2.1 Pre-assessment and off-site activities

2.1.1 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 MDCG 2021-15[6] for designation under the MDR, and/or
- form MDCG 2021-16[7] for designation under the IVDR.

The content of the application will include a specification of the conformity assessment activities and types of devices to be covered by the designation, using the codes set out in Implementing Regulation (EU) 2017/2185[8] and specified in the corresponding MDCG form (MDCG 2021-17[9] or MDCG 2021-18[10]).

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and NBs (for general information on "Member States" see https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.main).

3 Regulation (EU) 2017/745 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 (OJ L 117, 5.5.2017, p. 1).

4 Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

5 According to Art. 11(11) MDR and 40(11) IVDR, the Commission is empowered to adopt delegated acts modifying the frequency at which the complete re-assessments are to be carried out.

6 MDCG 2021-15 Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices regulation (MDR).

7 MDCG 2021-16 Application form to be submitted by a conformity assessment body when applying for designation as notified body under *the in vitro* diagnostic devices regulation (IVDR).

8 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

It is strongly recommended that CABs submit the application documentation/files taking account of the format considerations described in section 2.1.3 below to easily facilitate the transmission of the application by the designating authority to the Commission.

The language in which the application is made available will usually be one of the official languages of the Member State and/or one accepted by the designating authority. Nevertheless, it is usually the case that CABs with international clients or international personnel already have many procedures and related documents in English. Therefore, in order to facilitate the assessment of the application by the JAT, the CAB should also include in the application copies of any documents that are already available in English, in particular the quality manual, procedures related to qualification of personnel and procedures related to the process of conformity assessments. If these documents are not available in English, the CAB may provide additional courtesy copies of them translated into English. If applicable, these additional courtesy copies should be indicated or marked as such in order to be clear that they are not actually part of the CAB's quality management system.

CABs applying for designation should be aware of the time needed for the assessment of the application, execution of the on-site assessment, assessment of the subsequent correction and verification activities, designation, and, notification. The overall timing of the process depends very much upon the activities to be carried out by the CAB and relevant designating authority within the process itself. CABs should also note that whereas the assessment of a CAB is carried out by the national designating authority together with a JAT, it is the designating authority that is entrusted with liaising with the CAB. In contrast, the JAT liaises with the designating authority.

The flowchart in Annex 1 to this guide illustrates the process and an estimated length of time for each of its steps, including the legal timelines defined in the MDR/IVDR.

2.1.2 Designating authority's check of CAB's application for completeness

The designating authority will carry out an initial check after receipt of the application to verify the completeness of the CAB's application. The designating authority should indicate in the same application form(s) used by the CAB (see section 2.1.1) if all documents have been submitted as required (by ticking the relevant boxes). If one or more documents have not been submitted but the application is considered to be complete by the designating authority, it should provide a brief explanation as to why. For this purpose, the designating authority should fill in the box provided in the last page of the relevant form(s).

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 (OJ L 309, 24.11.2017, p. 7).

[9] MDCG 2021-17 Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR).

[10] MDCG 2021-18 Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR).

The completeness check must be carried out within 30 days after receipt of the application[11]. In the event that information is missing, the designating authority will request this information to the CAB within these 30 days. It is recommended that designating authorities set a deadline for the submission of the missing information and record such additional information / documents either on a separate list or by amending the application form.

According to its own procedures, if after a number of rounds of correspondence with the CAB the requested information is not forthcoming or it is still incomplete, the designating authority may decide to stop the completeness check of the application and inform the CAB of the need to re-apply for designation.

2.1.3 Transmission of the application to the Commission

Once the completeness check has been finalised and the application has been considered complete, it will be sent by the designating authority to the European Commission's Directorate-General for Health and Food Safety, (hereafter, DG SANTE) by e-mail (sent to the functional mailbox SANTE-F-MEDICAL-DEVICES@ec.europa.eu[12]). In case the application is not accepted by the designating authority, this should be informed to DG SANTE.

All of the documentation/files contained in the application need to be sent in electronic format, preferably taking into account that the files[13]:

- are in searchable pdf, or docx format[14];
- are provided once (e.g. if a document relates to several different topics in the application it should be provided only once and referenced appropriately within the application form);
- do not exceed 10 MB (including compressed/zipped files);
- have file names no longer than 50 digits (including extensions);
- do not contain (sub)-folders (for compressed/zipped files).
- are easily identifiable and retrievable and appropriately cross-referenced to the applicable areas within the application form as described in section 2.1.1. If possible, either the documents/files themselves should be consecutively or progressively numbered (e.g. from 001 to 999) or a stand-alone table providing this information should be included.

This transmission will normally be carried out by e-mail or, preferably, via a secure file-transfer platform. If the CAB has used an encryption method to submit the application documents to the designating authority (e.g. an encrypted CD, DVD or memory stick), the CAB could request that the designating authority uses the same form of

11 Articles 39 (1) of the MDR and 35 (1) of the IVDR.

12 All the e-mail exchanges with DG SANTE referred to in this guide are to be made to and from the functional mailbox SANTE-F-MEDICAL-DEVICES@ec.europa.eu

13 The listed limitations are necessary to ensure compatibility with CIRCABC, DG SANTE archiving features and for document translation purposes.

14 The other formats accepted are .ppt, .html, .htm, .xhtml, .rtf, .xlsx, .xml, .xilf, .xilff, .tmx, .txt, .odt, .ods, .odp, .odg, .ott, .ots, .otp, .otg.

transmission for security reasons. The designating authority may also send the data via registered postal mail to DG SANTE[15].

Once the application is received, DG SANTE will acknowledge its receipt via e-mail to the designating authority. Designating authorities may consecutively inform the CAB of submission of the application to DG SANTE.

2.1.4 Review of the application by the designating authority (including completion of the preliminary assessment report)

The designating authority will review the application(s) and supporting documentation according to its own procedures. There is no time limit established in the MDR and/or IVDR for this review, although the estimate is that this detailed assessment is completed within 3 months of finalisation of the completeness check.

The assessment will take into consideration the requirements under Annex VII to the MDR or IVDR and also any other applicable requirements of this Regulation and related Implementing and Delegated Regulations. The outcome of this exercise is to be documented, preferably in English, in the preliminary assessment report (form NBOG F 2017-5[16] or NBOG F 2017-6[17]).

Where clarification is needed, the designating authority will request the CAB to provide further information within a predefined deadline.

According to its own procedures, if after a number of rounds of correspondence with the CAB the requested information is not forthcoming or is still unsatisfactory, the designating authority may terminate the application procedure and inform the CAB of the need to re-apply for designation. In such cases, the designating authority should inform DG SANTE by e-mail.

It must be emphasised that the receipt of this preliminary assessment report by the Commission (see section 2.1.5) will trigger the appointment of a JAT, and the subsequent scheduling of the corresponding on-site assessment (see section 2.1.6). Therefore, it is of the utmost importance that the designating authority makes sure that the outcome of the review is sufficiently satisfactory as to substantiate the conduct of an on-site assessment[18].

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15 Postal mail needs to be sent to the following address:
European Commission
Directorate-General for Health and Food Safety (DG SANTE)
Directorate F: Health and food audits and analysis
Grange, Dunsany C15, DA39, Co Meath. Ireland

16 NBOG F 2017-5 Preliminary assessment report form – Regulation (EU) 2017/745.

17 NBOG F 2017-6 Preliminary assessment report form – Regulation (EU) 2017/746.

18 The application needs to show that the CAB has sufficiently addressed all the applicable requirements before the on-site assessment can be scheduled.

2.1.5 Transmission of the preliminary assessment report

The designating authority needs to submit via e-mail the preliminary assessment report to DG SANTE (preferably in word format) which will immediately transmit it to the MDCG by means of uploading it into the MDCG CIRCABC[19] dedicated workspace[20]. The designating authority should also submit copies of documents that were updated or newly created after submission of the application to the Commission (section 2.1.3 above) and should clearly indicate if new documents are included, if any documents included in the original application are no longer valid and if any original documents are to be replaced by the amended ones. Further submission of updated or new application documents (after the transmission of the PAR and before the on-site assessment) is, in principle, not acceptable (see section 2.1.11 below).

In order to allow for the scheduling of the corresponding on-site joint assessment, the designating authority needs to inform DG SANTE about preferred dates for the on-site assessment and dates on which the on-site assessment cannot take place[21] taking into account the 90 days allowance for the JAT to review the documentation submitted with the application[22]. It is recommended that the designating authority also provides contact details for a coordinator with whom the JAT coordinator can liaise regarding subsequent steps in the process, e.g. provision of feedback on the preliminary assessment report.

DG SANTE will acknowledge receipt of the preliminary assessment report via e-mail to the designating authority. In case the preliminary assessment report has not been submitted in English, DG SANTE will arrange for a machine translation[23] (and also an official translation), which will be also transmitted to the MDCG via CIRCABC.

2.1.6 Appointment of the JAT and scheduling of the on-site assessment

Whilst there is no time limit in the Regulations for scheduling the on-site assessment of the CAB, following receipt of the preliminary assessment report, in order to prevent undue delays, DG SANTE will liaise with the designating authority in order to seek preliminary agreement on a proposal of tentative dates for the on-site assessment.

The scheduling of the on-site joint assessments will take into account:

- the date of receipt of the preliminary assessment report,
- the availability of the CAB,
- the availability of the designating authority,
- the availability of the suitable experts to be appointed as JAT members,
- the availability of interpreters provided by the Commission interpretation services (SCIC) in cases where translation will be required on-site,

[19] Communication and Information Resource Centre for Administrations, Businesses and Citizens.

[20] All the exchanges with the MDCG referred to in this guide are to be made by e-mail sent from the MDCG CIRCABC workspace, to which MDCG members as well as DG SANTE have access.

[21] These dates could relate to prior commitments of the designating authority or could have been communicated previously by the CAB to the designating authority.

[22] Article 39(4) MDR / Article 35(4) IVDR.

[23] DG SANTE will arrange for machine translations using the Commission's machine translation software.

- the content of the preliminary assessment report, and
- the 90 days allowance for review of the PAR by the JAT.

It is essential that the on-site assessment lasts long enough so that both the designating authority and the JAT can effectively assess whether the CAB fulfils the requirements throughout its applied-for scope of designation, and sufficient time is allowed for internal discussion of findings. Therefore, on-site assessments will normally require 40 hours, which may be adjusted depending on the size of the CAB, the applied-for scope of designation and the requirement for interpretation. The number of hours referenced should be understood as actual assessment time. In case there is a need to schedule further time to complete the on-site assessment (e.g. if subsidiaries or subcontractors are included in the process), this should be communicated by the designating authority to DG SANTE in advance.

DG SANTE will highlight any issues to the designating authority (and MDCG if applicable) that could prevent or delay the scheduling of the on-site assessment in accordance with the afore-mentioned criteria. Notably, these issues could concern an insufficient content of the preliminary assessment report, or a preliminary assessment report showing that the CAB's documentation is unsatisfactory.

Within 10 days following receipt of the preliminary assessment report, DG SANTE will communicate a proposal for appointment of a JAT to the MDCG[24].

The JAT will usually include two experts from DG SANTE (one of whom will act as JAT coordinator) and two national experts (from two Member States other than the one of the CAB)[25]. DG SANTE will propose national experts who are best suited (on the basis of their field of competence and expertise in relation to the CAB's applied-for scope of designation and language capabilities) and are available to participate effectively in the on-site assessment. In specific circumstances, and on a case-by-case basis, a different number of experts could be proposed, for instance for training or calibration purposes. The proposal will also explicitly indicate the JAT's appointment due date (i.e. 14 days following the reception of the preliminary assessment report by the Commission[26]), as well as the date by which MDCG members should notify DG SANTE of any need for clarifications and/or objections to the proposal (usually, 3 days after the proposal is made).

Requests for clarifications from MDCG members (e.g. comments or questions) will be addressed bilaterally by DG SANTE, while objections will be brought to the attention of all MDCG members, with a view of seeking a common MDCG position.

[24] MDCG members will receive an automatic notification from CIRCABC upon upload of the proposal. In addition, and given that it is reasonable to assume that MDCG members will be receiving also other notifications from CIRCABC, DG SANTE will arrange for the subsequent dispatch of a specific e-mail from CIRCABC, allowing MCDC members to immediately pinpoint that a JAT appointment proposal has been made.

[25] Articles 39(3) of the MDR and 35(3) of the IVDR. National experts will be selected from the pool made available according to Articles 40 of the MDR or 36 of the IVDR.

[26] As referred to in Articles 39(3) of the MDR and 35(3) of the IVDR.

Once the JAT's appointment due date has elapsed, if:

iii. there have been no request for clarifications and no objections have been raised,

iv. clarifications have been requested and they have been answered, and no objections have been raised, or

v. objections have been raised, and the MDCG has taken a common (favourable) position of the JAT proposal.

DG SANTE will upload, as soon as possible, a document setting out the formal appointment of a JAT in CIRCABC, following which the MDCG members will receive the corresponding automatic notification. This document will summarise comments / questions / objections received from MDCG members and a common position of the MDCG. Unless objections have been raised and followed up within the MDCG, a consensus will be assumed[27].

When a CAB applies at the same time for designation under both the MDR and the IVDR, given that it is not possible to combine both joint assessments in a week (e.g. as different expertise of the JAT members will be required for each assessment), DG SANTE will schedule the assessments under each of the Regulations based on the availability of national experts. When the subsequent on-site assessment is scheduled approximately within the following 12 months, it should be possible to reduce its duration, provided that the documentation submitted under both Regulations is essentially the same (e.g. documentation relating to organisational and general requirements, and quality management system documentation).

2.1.7 Changes in the appointment of the JAT

Any circumstance that could have an impact on the conduct of the on-site assessment (e.g. modification on the number of days due to unexpected situations; change in date due to unavailability of interpreters after the JAT appointment) or changes to the JAT composition (e.g. last minute cancellation by one of the experts due to sickness), will be communicated immediately to the designating authority concerned and the MDCG, alongside, where applicable, the corresponding risk mitigation measures taken or proposed by DG SANTE.

Should a national expert who had been appointed as member of a JAT be no longer in a position to undertake his/her duties prior to the on-site assessment occurring, where feasible, the designating authority which has nominated that expert should submit to DG SANTE the name of another national expert who could take over this JAT member's role and, ideally, tasks. Subsequently, and taking account of this nomination and the availability of other suitable experts, DG SANTE will notify an (amended) composition of the JAT to the MDCG.

In cases where a national expert ceases to be available as a JAT member after the on-site assessment has been carried out, the joint assessment process will continue with

[27] The above-described procedure for the appointment of JATs was communicated to MDCG members on 16/03/2018, following its adaptation in response to a number of issues raised during the MDCG meeting of 6/03/2018.

the remaining members of the JAT[28] as long as at least one national expert still comprises part of the team. If this condition is no longer met, the MDCG will decide on a case by case basis on how to proceed.

Changes affecting the JAT composition relating to DG SANTE members as well as other occurrences (for instance, changes in the tentative dates of or venue for the on-site assessment) will also be communicated to the MDCG.

2.1.8 Announcement of the on-site assessment

After the JAT has been appointed and the dates of the on-site assessment have been agreed by the parties involved, DG SANTE will formally announce the on-site assessment to the designating authority, including its dates and the composition of the JAT. This formal letter will, ideally, be sent out at least 3 months prior to the on-site assessment and will include a specimen assessment plan for the on-site assessment. In parallel, DG SANTE will send formal invitation letters to the national experts participating in the JAT.

If the language in which the on-site assessment is to be conducted is not English or the relevant documentation to be reviewed is not available in English, DG SANTE will arrange for interpretation to be provided at the Commission's expense. This information will be communicated to the designating authority.

2.1.9 Dissemination of information to JAT members

As soon as the JAT has been appointed, DG SANTE will upload the information referred to in sections 2.1.3 and 2.1.5 (including machine translations of appropriate documents that were not submitted in English or in a language readily understandable by the JAT) into the SANTE/F CIRCABC dedicated workspace in order to disseminate it among the JAT members, who will be granted access to this workspace via their CIRCABC profiles.

2.1.10 Assessment of the application by the JAT

The JAT will review the CAB's application and supporting documents and will document this review using the preliminary assessment report template (NBOG F 2017-5 or NBOG F 2017-6). Within 90 days of the appointment of JAT, the JAT may require clarifications on the application and supporting documents from the designating authority, if needed. The JAT coordinator will make every effort to ensure that the assessment of the application is conducted on time. National experts are expected to be actively involved in, and contribute to, this process. Therefore, specific parts of the assessment may be assigned to the national experts, taking into account their field of expertise.

[28] As agreed during the MDCG meeting on 24-25/09/2018.

Within the 90 day review period of the PAR by the JAT, the JAT coordinator will usually provide detailed feedback of such a review to the designating authority concerned by e-mail. The designating authority will use this feedback when finalising a proposed assessment plan, which will be sent to the JAT coordinator.

2.1.11 Coordination between the designating authority and the JAT

The JAT coordinator will be responsible for establishing and maintaining contact with the designating authority (usually by e-mail exchanges). Once the off-site assessment by the JAT has been completed and, when possible, at least 2 weeks prior to the on-site assessment, the JAT coordinator will organise a teleconference (or any alternative arrangement, for example e-mail exchanges) between the designating authority team and all of the JAT members, for the purpose of:

- discussing the results of the off-site assessments of the application carried out both by the designating authority and the JAT,
- addressing open questions on the application,
- agreeing on the role of each member of the overall assessment team (i.e. the designating authority team and the JAT) during the on-site assessment, and
- agreeing on the designating authority's proposed assessment plan.

Following the above discussion, if required, the designating authority will update the assessment plan and forward it to the CAB and the JAT coordinator.

The CAB should ensure that there are no changes in the application supporting documents once the designating authority has finalised its preliminary assessment. However, if changes are made to the supporting documents after submission of the preliminary assessment report, the CAB needs to send the amended versions to the designating authority highlighting any difference with the documentation submitted in the initial application, and provide a rationale for those changes made. The designating authority will inform the JAT about these changes as soon as possible but no later than during the above-mentioned teleconference and an agreement should be reached about which are the amended documents that should be sent to the JAT coordinator prior to the on-site assessment. This submission should also clearly indicate if new documents are included, if any documents included in the original application are no longer valid and which documents should be replaced by the amended ones. The designating authority should also inform the CAB to present a documented list of the affected documents highlighting the changes made to the JAT at the beginning of the on-site assessment. In case of failure of the electronic systems, it is recommended that the CAB has available a full back-up set of application documentation / files ready for consultation and scrutiny if required.

2.2 On-site-assessment activities

2.2.1 Scope and organisation of the on-site assessment

The on-site assessment will be led by the designating authority team. The JAT will be included in the overall assessment team and will actively participate in the assessment, asking for any clarification or further documentation to be provided by the CAB at any time.

The on-site assessment will cover all of the designation requirements laid down in Annex VII to the MDR or the IVDR and also any other applicable requirements of this Regulation and related Implementing and Delegated Regulations. It should be noted that the issuance of certificates following the process described in Articles 16 MDR/IVDR and 17 MDR are not considered conformity assessment activities under Annexes IX to XI and therefore will not be part of joint assessments. However, the designating authority itself may carry out its assessment of these activities separately in parallel as long as this will not negatively impact the conduct of the assessment.

The on-site assessment will follow the agreed assessment plan. Every effort should be made to respect the pre-defined starting and finishing times indicated in this assessment plan.

In order to avoid lengthy sessions in the CAB's premises, where possible, evening coordination meetings between the designating authority team and the JAT should be planned to take place in another location.

2.2.2 Opening meeting

Prior to the opening meeting of the on-site assessment, the designating authority team and the JAT may hold a coordination meeting, aimed at clarifying any outstanding issues, confirming the role of each member of the overall assessment team, and sorting out practicalities for the conduct of the on-site assessment.

The opening meeting of the on-site assessment will be led by the designating authority team. An outline of the following aspects will be covered:

- legal basis for the assessment,
- confirmation of the applied-for scope,
- introduction of the members of the designating authority team and the JAT,
- brief description of the designation process, and
- confidentiality rules.

After the above aspects have been covered, the CAB will be given the floor to make a brief presentation of its organisation, and to introduce the personnel who will participate in the on-site assessment. The CAB could also seek clarifications on any of the above-mentioned aspects. The JAT could take the floor at any time of the opening meeting to provide clarifications or further information about the above-mentioned issues.

2.2.3 Conduct of the on-site joint assessment

The designating authority team and the JAT will split into two (or more) sub-teams in order to cover the assessment of the four main subject areas detailed in Annex VII to the Regulations, namely organisational and general requirements, quality management system requirements, resource requirements and process requirements. The experience and competence of the JAT team members will be taken into account when assigning members to sub-teams. Usually, one sub-team (typically assessors of the designating authority together with the JAT coordinator) will focus on the said four main subject areas, whereas other sub-team(s) (typically the national experts and, if necessary, members of the designating authority and DG SANTE) will focus on the assessment of the CAB's personnel files. Each team may be supported by interpreters.

Where possible, and agreed with the designating authority, the JAT member(s) within the sub-team(s) focussing on the assessment of personnel will be allowed to work individually to ensure an efficient use of time. This approach requires that the designating authority is informed of progress on a daily basis, that the outcome of these assessments is documented, and that the CAB has sufficient personnel to clarify the questions from each member of the overall assessment team.

Constant communication between the designating authority team and the JAT needs to be ensured throughout the on-site assessment, with time allocated for coordination meetings at the beginning of, during and/or at the end of each day's activities, in order to discuss the findings. The designating authority team may also decide to debrief the CAB at regular intervals during the assessment (either at the end of each day or at the beginning of the next day).

The conduct of the on-site assessment could reveal the existence of different interpretations of the legal requirements by the designating authority team and the JAT. In such cases, the discussion on these different interpretations will not be held in the presence of the CAB personnel. Instead, the matter will be put on hold and discussed in a coordination meeting between the designating authority team and the JAT, with a view to reaching consensus based upon agreed MDCG positions, if available. If consensus cannot be reached, the different interpretations will be formally documented as diverging opinions[29] (see section 2.3.1).

2.2.4 List of non-compliances

In case any shortcomings are found in the CAB's documentation or performance, these will be raised as non-compliances against legal requirements (for example, an article or a clause of the MDR or the IVDR). Findings pertaining to specific documents or individual files would be recorded as examples or supporting evidence for the non-compliances identified. Non-compliances should be classified (e.g. major or minor) to distinguish between those where the corrective actions have to be successfully

[29] Different views between the designating authority and the JAT might include but not be limited to: i) additional non-compliances, including non-compliances that are listed by the designating authority as observations, ii) different wording only in case that it could influence the relevance or the grading of the non-compliances, and/or iii) actual and potential diverging interpretations of the legislation, which should be further explored.

implemented by the CAB and verified by the designating authority before the decision on designation may be taken and those that may be verified after designation. When there is no legal requirement breached, findings should be classified as observations.

On a daily basis, the JAT coordinator will collate the non-compliances gathered by all of the JAT members, and provide them either verbally or in writing to the designating authority team, with a view to discussing these non-compliances during coordination meetings. The designating authority team may take this list as a basis for its final list of non-compliances or may draft its list according to the designating authority's own procedures.

Before the closing meeting with the CAB, the designating authority team will provide its written list of non-compliances to the JAT. Subsequently, there will be a coordination meeting between the designating authority team and the JAT, with a view to reaching consensus on the list of non-compliances and resolving any diverging opinions.

Following this coordination meeting, the list of non-compliances may be amended if necessary. Therefore, it is recommended that grading of findings with a view on the expected action by the CAB is clearly agreed on-site by the designating authority and the JAT. Any outstanding diverging views with respect to the outcome of the assessment (e.g. on individual non-compliances, legal interpretations and/or the overall outcome of the assessment) will be documented in the summary assessment report by the JAT, including any remaining diverging opinions[30], following the on-site assessment (hereafter, *JAT summary assessment report* – see section 2.3.1).

2.2.5 Closing meeting

The closing meeting will be led by the designating authority who will have the responsibility to provide the CAB and the JAT with its list of non-compliances[31] resulting from the assessment. The following points may be included:

- re-confirmation of the applied-for scope (in case of any change made during the on-site assessment),
- list of non-compliances resulting from the assessment,
- remaining diverging opinions,
- brief description of the designation process after the on-site assessment,
- requirement of the CAB to provide a corrective and preventive action (CAPA) plan within a specific deadline, and
- repeating the confidentiality rules.

In addition, the JAT coordinator will summarise the JAT assessment and/or comment on the outcome of the assessment. In particular, remaining diverging opinions should

[30] Diverging views between JAT members will be similarly documented.

[31] The designating authority might present its list in the official language of its Member State.

be brought to the attention of the CAB by the designating authority or, should the designating authority agree, by the JAT[32].

Any changes introduced by the designating authority to its list of non-compliances should be sent in writing within 5 working days after the on-site assessment to the JAT coordinator and, if needed, discussed with the JAT prior to its submission to the CAB.

This final version and an official translation, if required, will be uploaded into the CIRCABC dedicated workspace by DG SANTE.

2.2.6 CAPA plan: deadline for submission and content

At the end of the on-site assessment, the designating authority will require the CAB to provide a CAPA-plan within a specific deadline. In order to set this deadline, the designating authority should take into account the seriousness and complexity of the non-compliances identified, (e.g. root cause analyses of system related non-compliances could identify a number of causes that would require a wide range of actions to be implemented in different areas).

Ideally, the CAB will provide the designating authority with a complete CAPA plan as soon as possible and not later than 3 months after the on-site assessment.

The designating authority needs to inform the CAB about the minimum information that needs to be included in the CAPA plan in relation to each non-compliance identified in the final list of non-compliances, namely as follows:

- The root cause(s) of non-compliances, taking into account that often more than one cause will be the root of the deficiency.
- Corrections and CAPAs for each of the root causes identified. The deadline for its implementation should be specified.
- The actions planned by the CAB to verify the effectiveness of each CAPA and the timeframe for its review (e.g. internal audit, witness audits to monitor competence, etc.).

2.2.7 Problems in completing the on-site assessment

In exceptional cases, it may not be possible to assess the CAB's compliance against all of the designation criteria in the time allocated to the on-site assessment or due to the lack of evidence to be assessed. In such cases, the designating authority and the JAT will discuss the options available to ensure that all of the designation criteria are assessed with sufficient depth. Such options could include continuing the on-site assessment at a mutually agreeable future date.

If the designating authority disagrees with the JAT and considers that the assessment has covered all of the requisite areas in sufficient depth and thus does not agree to

[32] Where there is a diverging opinion for instance if the designating authority has not included in its list a non-compliance raised by the JAT, it is expected that this situation will be brought to the attention of the CAB as a diverging opinion in the closing meeting.

extend the duration of the assessment, this disagreement will be recorded in the *JAT summary assessment report* (see section 2.3.1).

2.3 Post on-site assessment activities

2.3.1 JAT summary assessment report

The JAT coordinator, in agreement with the rest of the JAT team, will issue the draft *JAT summary assessment report* (i.e. summary assessment by the JAT, including any remaining diverging opinions, following the on-site assessment) and formally submit it to the designating authority within 30 days of completion of the on-site assessment together with the applied-for scope that was assessed during the on-site assessment and should be used as the basis for the designating authority's designation.

The draft *JAT summary assessment report* will be produced taking into account the assessment made by the JAT and the designating authority's list of non-compliances received at the closing meeting (see section 2.2.5). In addition, the draft *JAT summary assessment report* should document any disagreement of the JAT in relation to the presentation of the list of non-compliances and/or the summary of the *JAT assessment* made by the designating authority team at the closing meeting. Within 25 working days of receipt of the draft *JAT summary assessment report*, the designating authority may comment thereon, in particular it could provide clarifications and/or confirm its views. As the applied-for scope cannot be further amended after the on-site assessment (with the exception of deletion of codes and addition of limitations) the designating authority should also highlight, if applicable, any errors in the attached applied-for scope which otherwise will be considered as final (this check is especially important when a new version with (limited) changes has been provided after the initial application). This applied-for scope will be the basis for the designating authority's decision on designation.

If necessary, the JAT coordinator will update the draft *JAT summary assessment report* taking into account the above-mentioned input from the designating authority. The final *JAT summary assessment report*, including any remaining diverging opinions, following the on-site assessment will be submitted to the designating authority within 15 working days following receipt of the comments or lack thereof.

2.3.2 Assessment of the CAPA plan by the designating authority

Upon receipt of the CAPA plan from the CAB, the designating authority will confirm it by means of assessing whether each non-compliance (and diverging opinion, if applicable) identified during the assessment has been appropriately addressed. This may be documented in the CAPA form. In order to carry out this task, the designating authority should verify that:

– all non-compliances raised in the on-site assessment are included in the CAPA plan,

– the root cause(s) of all non-compliances has/have been appropriately identified and assessed,
– corrections have been identified and implemented, where appropriate,
– CAPAs have been identified for each of the root causes, as well as the deadline for their implementation, and
– to verify the effectiveness of each CAPA have been identified, as well as the timeframe for its review.

For each non-compliance, the designating authority should classify the actions proposed (and deadlines for their implementation) as follows:

– **Satisfactory:** When root cause analysis has been properly conducted, corrections, CAPAs and deadlines for their implementation have been considered adequate, and processes proposed for verifying the effectiveness of such actions have been satisfactorily defined.
– **Unsatisfactory:** Whenever the information provided by the CAB is not sufficiently clear or relevant information is missing, or it is deemed to be inadequate or insufficient to address the non-compliances and/or prevent their recurrence. The designating authority should explain the rationale for this classification, which elements need to be further clarified and/or which information has to be provided by the CAB, including applicable deadlines.

If there are CAPAs that have been classified as unsatisfactory, the designating authority will ask within a specified deadline the CAB for a revised CAPA plan, which should address the above-mentioned issues. The designating authority may need several rounds of assessment for clarification and verification of the CAPA plan.

Where no CAPA plan or clarifications or modifications thereof have been received by a specified deadline, a new deadline could be established for the submission of this information. If after a number of rounds of correspondence with the CAB the requested clarifications are still missing or are unsatisfactory, the designating authority may decide according to its own procedures to stop the assessment of the application. In such cases, the designating authority should inform DG SANTE.

Ideally within 20 working days of having received and assessed the CAPA plan (including its revision, where applicable), the designating authority will confirm the CAPA plan and draft its *opinion on the CAPA plan*. This opinion will indicate, for each non-compliance, whether the proposed actions and deadlines for their implementation are considered satisfactory or unsatisfactory.

The confirmed CAPA plan[33] and the designating authority's opinion thereon will be forwarded by the designating authority to DG SANTE[34]. According to its own procedures, the designating authority may inform the CAB that the confirmed CAPA

[33] If the CAPA plan is not provided in English or a bilingual format with an English translation acceptable for the designating authority, it should be provided in both pdf and docx versions. In any case SANTE F and the JAT will assume that the content of the 2 formats is identical and will send the DOC to the commission translation services for official translations; however SANTE F will immediately machine translate the CAPA in order to allow the JAT to start its appraisal as soon as possible.

[34] If possible, the designating authority should inform the JAT coordinator about the expected timing when the CAPA plan will be forwarded well in advance.

plan and the designating authority's opinion thereon has been forwarded to DG SANTE.

If the CAPA plan is not deemed to be satisfactory in a given period of time, the designating authority may consider the possibility of not proceeding with the assessment.

2.3.3 JAT review of the CAPA plan

DG SANTE will acknowledge receipt of the CAPA plan via e-mail to the designating authority.

After receiving the CAPA plan and the designating authority opinion thereon, the JAT coordinator will arrange for their official translation (if needed). However, in order to allow the JAT to begin its appraisal as soon as possible, DG SANTE will immediately machine translate the documents and subsequently submit them to the national experts in a language that could be readily understood by the team. If the CAPA plan is submitted in English or in a bilingual format with an English translation acceptable for the designating authority, the JAT will assess the CAPA plan without the need for official translation, and therefore eliminating the time required for official translation of the documents (which may take 2-3 months).

Ideally within 5 working days, the JAT coordinator will forward the CAPA plan and designating authority's opinion to the national experts for their comments. All comments will be collated in a consolidated version by the JAT coordinator.

Following the above step, and ideally within 40 working days, provided that the official translation (when applicable) is available, the JAT should provide the designating authority with the *JAT CAPA review*, which will include its appraisal of the CAPA plan and of the designating authority's opinion thereon. The JAT will indicate whether:

- the CAPA plan (including the root cause analyses) is accepted and deemed in line with the requirements of the Regulations, and/or
- clarifications are needed (e.g. updated/new documents or information providing details of changes made), and/or
- whether any of the actions are not deemed as acceptable.

2.3.4 Feedback to the CAB on the assessment of CAPA plan

Following the receipt of the *JAT CAPA review*, the designating authority should finalise its assessment of the CAPA plan and provide the CAB with feedback. In case the CAB is requested to amend the CAPA plan, the designating authority should establish a deadline for these amendments.

Where clarifications and/or modifications of the CAPA plan have been requested by the JAT, the designating authority should update its assessment and will repeat the procedure referred in 2.3.2 until it is satisfied with the content of the CAPA plan. The designating authority will keep DG SANTE informed about the subsequent progress in the implementation, verification and assessment and of the CAPA plan. A number of iterations of the CAPA plan may be submitted and reviewed between the designating authority and the JAT before all issues have been clarified and addressed.

2.4 Decision on designation

2.4.1 Final review of the implementation of the CAPA plan to address the non-compliances prior to designation decision

The designating authority will need to verify the progress on the implementation of all CAPAs before taking a decision on designation, namely whether non-compliances have been closed or they need to be followed-up, where applicable:

- Closed: If the designating authority has verified the implementation of the relevant CAPAs and the verification of effectiveness of such actions have been finalised through documented evidence(s) and/or on-site follow-up assessment(s).
- To be followed-up[35]: The follow-up date should be specified by the designating authority for actions that are to be implemented according to a satisfactory schedule and/or for actions that had been already implemented but for which the verification of effectiveness is still to take place.

In assessing the implementation of the CAPA plan and the fulfilment of conditions for designation, the designating authority should consider the following:

- Non-compliances that should be implemented prior to designation: The implementation of the proposed actions needs to be verified by the designating authority prior to the issuing of the final assessment report[36]; the effectiveness of these actions may be verified by the designating authority following designation[37]
- Other non-compliances: the implementation of the proposed actions and their effectiveness may be verified by the designating authority following designation.

2.4.2 Designating authority's final assessment report

There is no time limit for the production of the designating authority's final assessment report. This is because: i) the number of non-compliances identified will influence the time that the CAB will need to put in place corrections and CAPAs, and ii) depending on the nature of non-compliances identified, the CAB will need to implement CAPAs before the designating authority produces its final assessment report.

The designating authority's final assessment report needs to contain, as a minimum, the following elements:

- the result of the assessment, including the list of non-compliances;
- confirmation that the corrections and CAPAs have been appropriately implemented and verified, where required:

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35 Contingent to the nature of the non-compliances, subsequent verification by the designating authority can take place after designation. This verification should take place during surveillance assessment or at an earlier stage through on-site follow up assessment or off-site assessment of documented evidence(s) provided by the CAB.

36 As defined in Articles 39(7) of the MDR and 35(7) of the IVDR.

37 For instance, for non-compliances concerning availability of sufficient qualified personnel, the corrective action (e.g. hiring of new qualified staff) will have to be implemented by the CAB and verified by the designating authority before designation. However, the CAB could verify the effectiveness of this type of CAPAs later on (e.g. by an internal audit with assessment of technical documentation), and this effectiveness be subsequently verified by the designating authority during the next surveillance audit.

- ✓ for each of the non-compliances identified, the assessment of the corrections and CAPAs proposed by the CAB,
- ✓ where applicable, information on the designating authority's verification that the corrections and CAPAs have been implemented by the CAB,
- ✓ where required, information on the designating authority's assessment on the effectiveness of the CAPAs already implemented by the CAB,

- where applicable, any remaining diverging opinions with the JAT, and,
- where applicable, a recommendation on the CABs proposed scope of designation as set out in the corresponding MDCG form, including any conditions and sufficiently detailed information in case the recommended scope of designation differs to the CAB's applied-for scope of designation.

The language of the designating authority's final assessment report will usually be that of the Member State concerned. Nevertheless, the designating authority will fill in the corresponding *Key information document* (reference MDCG 2019-12[38]) in English, in order to allow the JAT and the MDCG to understand the outcome of the assessment and the post-assessment activities. Should the recommended scope of designation differ to the CAB's applied-for scope of designation, this should be explained also in this *Key information document*.

2.4.3 Submission of the final assessment report to the Commission

The designating authority needs to submit its final assessment report together with the *Key information document* and, where applicable, the CAB's draft designation to DG SANTE, which will immediately transmit it to the MDCG and the JAT. DG SANTE will acknowledge receipt of these documents via e-mail to the designating authority.

In respect of those designating authority's final assessment reports and, if applicable, CAB's draft designations which are not written in English, DG SANTE will arrange for a machine translation, which will be also transmitted to the MDCG.

According to its own procedures, the designating authority may inform the CAB that the final assessment report has been submitted to DG SANTE, together with the draft designation.

2.4.4 JAT final opinion

Within 21 days following receipt of the designating authority final assessment report and *Key information document* and, if applicable, the CAB's draft designation, DG SANTE will submit the *JAT final opinion* to the MDCG. The *JAT final opinion* will also be submitted to the designating authority.

The *JAT final opinion* will include, as applicable:

- a brief summary of the JAT assessment: the off-site review of the application (see section 2.1) and the on-site assessment (see section 2.2),

[38] MDCG 2019-12 Designating authority's final assessment form: Key information (EN).

- a brief summary of the JAT assessment of the CAPA plan and the designating authority's opinion thereon, including, if applicable, the JAT views on progress made in the implementation, verification and assessment of the CAPA plan (see section 2.3),
- the updated remaining diverging opinions and considerations as to whether these could have an impact on the MDCG's recommendation on designation (see section 2.4.5),
- the JAT opinion on the designating authority's recommended scope of designation and, if applicable the CAB's draft designation (see section 2.4.2).

For the purpose of reaching agreement on the *JAT final opinion*, the JAT coordinator will discuss the above-mentioned elements between all of the JAT members by means of organising a teleconference or any alternative arrangement, for instance e-mail exchanges. In exceptional circumstances, where consensus on the content of the *JAT final opinion* cannot be reached by all members of JAT, this will also be recorded.

2.4.5 MDCG's recommendation on the draft designation

Within 42 days of receipt of the *JAT final opinion*, the MDCG will issue a recommendation on the CAB's draft designation proposed by the designating authority.

For this purpose, the MDCG's chair will coordinate the preparation of a proposal for a recommendation on the draft designation, which will be shared with the members of the MDCG as soon as possible, for their comments. Considerations included in the *JAT Final Opinion* will be used as a basis for proposing the relevant MDCG Recommendation.

MDCG will be consulted on the proposed MDCG Recommendation on the draft designation of the CAB in accordance with the MDCG Rule of procedure[39]. The abovementioned proposed MDCG Recommendation can be either discussed during the MDCG meeting or processed via a written procedure. If needed, a dedicated meeting, either physical or virtual, may be set to discuss possible cases.

The final MDCG Recommendation endorsed by the MDCG will be uploaded in the dedicated CIRCABC Workspace and forwarded to the designating authority and all MDCG members.

2.4.6 Designating authority's final decision on designation

The designating authority will make its final decision on designation according to its own procedures. The MDCG's recommendation will be duly taken into consideration by the designating authority for its decision on the designation of the CAB.

[39] Medical Device Coordination Group is available here https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=3565

3 Notification and publication in NANDO

3.1 Notification in NANDO

Once the procedure described in section 2 above is completed, the designating authority will proceed with the notification of the designated CAB to the Commission and the other Member States. The notification must be done by using the specific electronic notification tool within the Commission's NANDO information system[40] (the "notifying authorities notifications module" of NANDO-Input).

3.2 Contents of the notification

The information to be submitted by the designating authority in NANDO will include:

- the name and postal address of the designating authority,
- the reference legislation: Regulation (EU) 2017/745 on medical devices or Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices,
- the identification of the CAB, with the name, postal address, telephone, e-mail and website,
- the scope of the designation, with the tasks to be performed by the CAB in terms of conformity assessment activities and the types of devices which the body is authorised to assess. The information must specify the vertical and the horizontal technical competences and the relevant product family / product intended use / product range, by using the codes reflecting the design and intended purpose of the device as defined in the Commission Implementing Regulation (EU) 2017/2185[41] (For the MDR: MDA for active devices, MDN for non-active devices, MDS for devices with specific characteristics and MDT for devices for which specific technologies or processes are used; analogous codes for the IVDR); the applicable conformity assessment procedure(s) / module(s) and the related Annex(es) of the concerned Regulation; and the conditions / restrictions associated with the designation, if any.

This information is collected by the system that generates the pdf format "Notification of a Body in the framework of a technical harmonization directive", which includes also the four-digit number assigned to the conformity assessment body[42], in the format "NB xxxx", as well as the date of the notification and the subsequent updates, if any.

When submitting a new notification, the designating authority will be also required to enter the date for the first re-assessment. It is recommended to enter an indicative date three years (+ 1 month) after the notification.

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40 New Approach Notified and Designated Organisations: https://ec.europa.eu/growth/tools-databases/nando/

41 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 (OJ L 309, 24.11.2017, p. 7).

42 See MDR Article 43(1) and IVDR Article 39(1).

3.3 Supporting documents

The notification in NANDO will be accompanied by a set of supporting documents:

- the designating authority's final assessment report (see 2.4.2),
- the JAT final opinion (see 2.4.4),
- the MDCG's recommendation on the draft designation (see 2.4.5),
- the designating authority's final decision on designation (see 2.4.6).

Supporting documents will also include designating authority's feedback on the MDCG recommendation as well as information about the monitoring activities. Such information can be included in the designating authority's final decision on designation. In particular, in case the MDCG recommendation includes any conditions, the designating authority will provide its feedback either confirming if and how specific conditions will be applied or providing a justification for not following it.

Information will be provided also concerning the evidence of the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to satisfy the applicable requirements. For example, the designating authority should ensure that:

- monitoring and re-assessment of the notified body will be performed in accordance to Article 44 of the MDR or Article 40 of the IVDR;
- surveillance assessments will be scheduled annually and on-site assessments / assessment of subsidiaries and subcontractors / observed audits will be included;
- the designating authority will review the notified body's assessment of manufacturer's technical documentation selected on a sampling basis.

3.4 Objection period

Once the notification is received and validated by the Commission in NANDO, the system sends an e-mail message to the authorities of the Member States, as the preliminary notification informing that a new notification from a designating authority has been encoded in NANDO, indicating the conformity assessment body name and number, and the concerned Regulation. The preliminary notification states that Member States have the opportunity to raise an objection, starting from the date of the e-mail notification, for a period of 28 calendar days, ending on a specific day. In the absence of any objection, the notification will be definitively validated and published by the Commission in the relevant section of NANDO, within 42 calendar days of the notification.

Objections may be raised by Member States or by the Commission. The MDCG will give its opinion on the objection, whether the notification can be accepted or confirming the objection, asking the notifying Member State to provide a written response addressing the objections and setting out the reasons for the decision to designate or not designate the conformity assessment body. When either the MDCG considers that the notification can be accepted despite the objections, or the notifying Member State decides to confirm its decision to notify the conformity assessment body, the

Commission will publish in NANDO the notification within 14 calendar days of the information.

3.5 Publication in NANDO and validity of the designation

When the notification is published in NANDO, the system sends an e-mail message to the authorities of the Member States, as the final notification informing that a new notification from a designating authority has been encoded in NANDO, indicating the conformity assessment body name and number, and the concerned Regulation. The message also provides the link to the full notification details as published in NANDO, with the information on the scope of the designation as collected in the pdf format "Notification of a Body in the framework of a technical harmonisation directive", presented in html format too.

The designation of the CAB becomes valid the day after the notification is published in NANDO. Once the designation has become valid, the conformity assessment body concerned may perform the activities of a notified body within the scope of the notification.

4 Re-assessments of notified bodies

In general, the process for the conduct of re-assessments of NBs will follow the same procedure as for designation assessments of applicant CABs. However, specific differences in the process are described below. In particular, in line with the aim and purpose of re-assessments and overall goals of the Regulations regarding safety of medical devices this guidance establishes procedural time limits for the conduct of the process.

4.1 Pre-assessment and off-site activities

Twice per year (ideally in January and July), the COM will send a letter to designating authorities informing them of the NB's on their territory that are eligible for re-assessment within the subsequent 12 months.

4.1.1 NB's documentation for re-assessment

In order to determine if NBs still satisfy the relevant requirements of the Regulations, in accordance with their own procedures designating authorities will request NBs to supply relevant information and documents[43] to enable them (and JATs) to verify compliance and conduct a complete re-assessment in the context of Article 44(10) of the MDR and Article 40(10) of the IVDR.

The content of the documentation will include a specification of the conformity assessment activities and types of devices covered by the NB's designation, using the

[43] MDR Article 44 (2) & IVDR Article 40 (2)

codes set out in Implementing Regulation (EU) 2017/2185[44] and specified in the corresponding MDCG form (MDCG 2021-17 or MDCG 2021-18), and should preferably also include:

- a list of certificates held by the NB,
- a copy of the matrix detailing the authorisations and responsibilities of the personnel in respect of conformity assessment activities,
- the quality management system documentation, including the management system structure and the list of all quality management system documents, and the sequence and interrelation of processes

NBs subject to re-assessment should be aware of the time needed for the assessment of the documentation, the execution of the on-site assessment and the subsequent verification activities. It is recommended that designating authorities request the NBs to submit the required documentation ideally 3-6 months before their eligibility for re-assessment (i.e. three years from the date of their initial notification for first re-assessments and every fourth year thereafter).

The flowchart in Annex 2 to this guide illustrates the process and an estimated length of time for each of its steps.

4.1.2 Designating authority's check of NB's documentation for re-assessment for completeness

An initial check is to be carried out by the designating authority to verify the completeness of the NB's documentation for re-assessment.

The completeness check will be carried out within 30 days after receipt of the documentation[45]. In the event that information is missing, the designating authority will request this information to the NB within these 30 days. It is recommended that designating authorities set a deadline for the submission of the missing information.

According to the designating authority's procedures, if after a number of rounds of correspondence with the NB the requested information is not forthcoming or it is still incomplete, the designating authority may decide to terminate the re-assessment process and inform the NB of the need to initiate activities in accordance with Article 46 (4) of the MDR and/or Article 42 (4) of the IVDR.

The transmission of the documentation for re-assessment to the Commission will follow the procedure outlined in section 2.1.3 above.

[44] 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 (OJ L 309, 24.11.2017, p. 7-17).

[45] Articles 39 (1) of the MDR and 35 (1) of the IVDR.

4.1.3 Review of the documentation for re-assessment by the designating authority

The designating authority will review the re-assessment documentation according to its own procedures.

The assessment will take into consideration the requirements under Annex VII to the MDR and/or IVDR and also any other applicable requirements of these Regulation(s) and related Implementing and Delegated Regulations including information relating to the NB's file reviews on manufacturers' technical and clinical documentation. Results of the monitoring and assessment activities of the designating authority may also be considered. The outcome of this exercise is to be documented, preferably in English, in the preliminary re-assessment report (PRAR).

It must be emphasised that the receipt of this PRAR by DG SANTE will trigger the appointment of a JAT, and the subsequent scheduling of the corresponding on-site assessment. To facilitate an efficient conduct of the on-site assessment, it is of the utmost importance that the designating authority makes sure that the outcome of their review is comprehensive.

Where clarification is needed, the designating authority will request further information to be provided by the NB within a predefined deadline.

Supplementary, the procedures outlined in sections 2.1.5 to 2.1.11 apply. Concerning the appointment of the joint assessment team, the team may or may not be comprised of experts involved in the previous assessment.

4.2 On-site assessment activities

4.2.1 Scope and organisation of the on-site assessment

In principle, the procedure outlined in section 2.2 also applies for on-site assessments carried out in the context of a re-assessment. The on-site assessment will be led by the designating authority team. The JAT will be included in the overall assessment team and will actively participate in the assessment, asking for any clarification or further documentation to be provided by the NB at any time.

The on-site assessment will include an assessment of the implementation of the designation requirements laid down in Annex VII to the MDR or the IVDR, including

- the NB's quality management system documentation,
- reviews of NB conformity assessment activities, including assessments of technical documentation and clinical documentation in accordance with Article 45(4) of the MDR and Article 41(4) of the IVDR, including the (related) NB's personnel files and
- any other applicable requirements of these Regulations.

Relevant changes to the NB's quality management system since their designation assessment / last re-assessment may also be reviewed.

The on-site assessment will follow the agreed assessment plan. Every effort should be made to respect the pre-defined starting and finishing times indicated in this assessment plan. In order to avoid lengthy sessions in the CAB's premises, where possible, evening coordination meetings between the designating authority team and the JAT should be planned to take place in another location.

Supplementary, the procedures outlined in sections 2.2.3 to 2.2.7 apply. However, during the on-site assessment the sub-team(s) comprising typically of the national experts and, if necessary, members of the designating authority and DG SANTE, will also focus on the reviews of the notified body assessments of technical and clinical evaluation documentation. In addition, the classification of non-compliances during re-assessments should depend on their importance and/or influence on the results of conformity assessments or the safety and performance of medical devices.

4.3 Post on-site assessment activities

The procedure outlined in section 2.3 applies.

4.4 Re-assessment conclusion

4.4.1 Final review of the implementation of the CAPA plan to address the non-compliances prior to deciding whether the NB still satisfies the requirements of the Regulations

The designating authority will need to verify the progress on the implementation of all CAPAs before deciding whether or not the NB still satisfies the requirements for designation, namely whether non-compliances have been closed or they need to be followed-up, where applicable:

- Closed: If the designating authority has verified the implementation of the relevant CAPAs and the verification of effectiveness of such actions have been finalised through documented evidence(s) and/or on-site follow-up assessment(s).
- To be followed-up[46]: The follow-up date should be specified by the designating authority for actions that are to be implemented according to a satisfactory schedule and/or for actions that had been already implemented but for which the verification of effectiveness is still to take place.

In assessing the implementation of the CAPA plan and the fulfilment of the requirements for notified bodies, the designating authority should consider the following:

- Minor non-compliances: the implementation of the proposed actions and their effectiveness may be verified by the designating authority at a later date.
- Major non-compliance (or multiple minor non-conformities on similar issues): the implementation of the proposed actions needs to be verified by the designating authority prior to the issuing of the final re-assessment report47; the effectiveness of these actions may be verified by the designating authority at a later date.

[46] Contingent to the nature of the non-compliances, subsequent verification by the designating authority can take place at a later date. This verification should take place during surveillance assessment or at an earlier stage through on-site follow up assessment or off-site assessment of documented evidence(s) provided by the NB.

[47] As defined in Articles 39(7) of the MDR and 35(7) of the IVDR.

4.4.2 Designating authority's final re-assessment report

The procedure outlined in section 2.4.2 applies. However, instead of including a recommendation on the CAB's proposed scope of designation, the designating authority's final re-assessment report will contain:

– the designating authority's conclusion on whether or not the NB still satisfies the relevant requirements of the MDR/IVDR, and

– where applicable, a recommendation on an amendment to the NB's scope of designation, including any conditions and sufficiently detailed information in case the newly recommended scope differs to the NB's scope of designation[48].

4.4.3 Submission of the final re-assessment report to the Commission

Within 2 months of ensuring that the CAPA plan has been appropriately implemented, the designating authority needs to submit its final re-assessment report together with the *Key information document* and, where applicable, the NB's draft amended designation to DG SANTE, which will immediately transmit it to the MDCG and the JAT. DG SANTE will acknowledge receipt of these documents via e-mail to the designating authority.

In respect of those designating authority's final re-assessment reports which are not written in English, DG SANTE will arrange for a machine translation, which will be also transmitted to the MDCG and the JAT.

4.4.4 JAT final opinion

The procedure outlined in section 2.4.4 applies.

However, in addition to the bullet points outlined in section 2.4.4 above, instead of including the JAT opinion on the designating authority's recommended scope of designation, the *JAT final opinion* will also include:

– the JAT opinion on the designating authority's conclusion on whether or not the NB still satisfies the relevant requirements of the MDR/IVDR and

– the JAT opinion on the designating authority's recommended amended scope of designation, if applicable.

4.4.5 MDCG's recommendation on the draft decision on continued designation

Within 42 days of receipt of the *JAT final opinion*, the MDCG will issue a recommendation on the NB's draft continued designation proposed by the designating authority.

The process described under 2.4.5 will be followed also in case of MDCG Recommendation on the continued designation of the notified body.

[48] In cases where a re-assessment results in a proposal for a newly recommended scope, the relevant process for changes to a designation (including notification) must be followed.

4.4.6 Designating authority's final decision on whether or not the NB still satisfies the requirements for designation

The MDCG's recommendation will be duly taken into consideration by the designating authority for its decision on whether or not the NB still satisfies the requirements for designation.

5 Update of notification in NANDO

Once the procedure described under 4 is completed, the designating authority should proceed with the update of the notification in NANDO. The designating authority may submit:

- the supporting documents listed under 4.4.3 with regard to the re-assessment process,
- the JAT final opinion (see 4.4.4),
- the MDCG's recommendation (see 4.4.5),
- the designating authority's final decision (see 4.4.6).

When updating the notification in NANDO, the designating authority will be required to enter the date for the next re-assessment. It is recommended to enter an indicative date of four years (+ 1 month) after the update of the notification.

6 References

References

Regulation (EU) 2017/745 Chapter IV

Regulation (EU) 2017/746 Chapter IV

Sources

[1] MDCG 2021-15 Application form to be submitted when applying for designation as a notified body under the medical devices Regulation (MDR)

[2] MDCG 2021-16 Application form to be submitted when applying for designation as a notified body under the *in vitro* diagnostic devices Regulation (IVDR)

[3] MDCG 2021-17 Applied-for scope of designation and notification of a Conformity Assessment Body form – Regulation (EU) 2017/745

[4] MDCG 2021-18 Applied-for scope of designation and notification of a Conformity Assessment Body form – Regulation (EU) 2017/746

[5] NBOG F 2017-5 Preliminary assessment report form – Regulation (EU) 2017/745

[6] NBOG F 2017-6 Preliminary assessment report form – Regulation (EU) 2017/746

[7] Preliminary re-assessment report form – Regulation (EU) 2017/745

[8] Preliminary re-assessment report form – Regulation (EU) 2017/746

[9] CAPA form

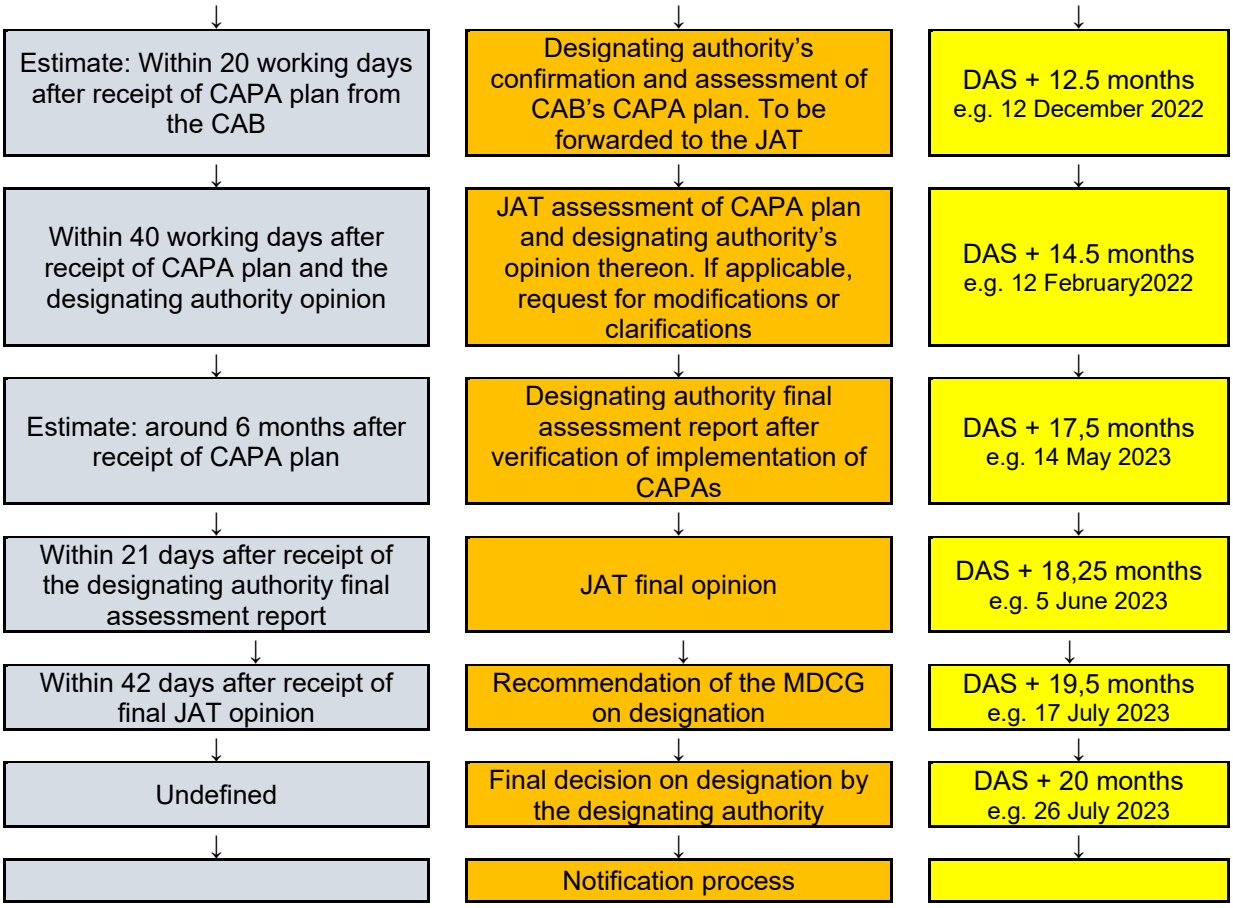
Keywords

CIRCABC, conformity assessment body, designating authority, designation, European Commission, JAT, joint assessment, MDCG, NANDO, notification, publication, Regulations, reporting, DG SANTE

Date of issue

Annex 1: Flowchart of activities and times: Designation Assessments

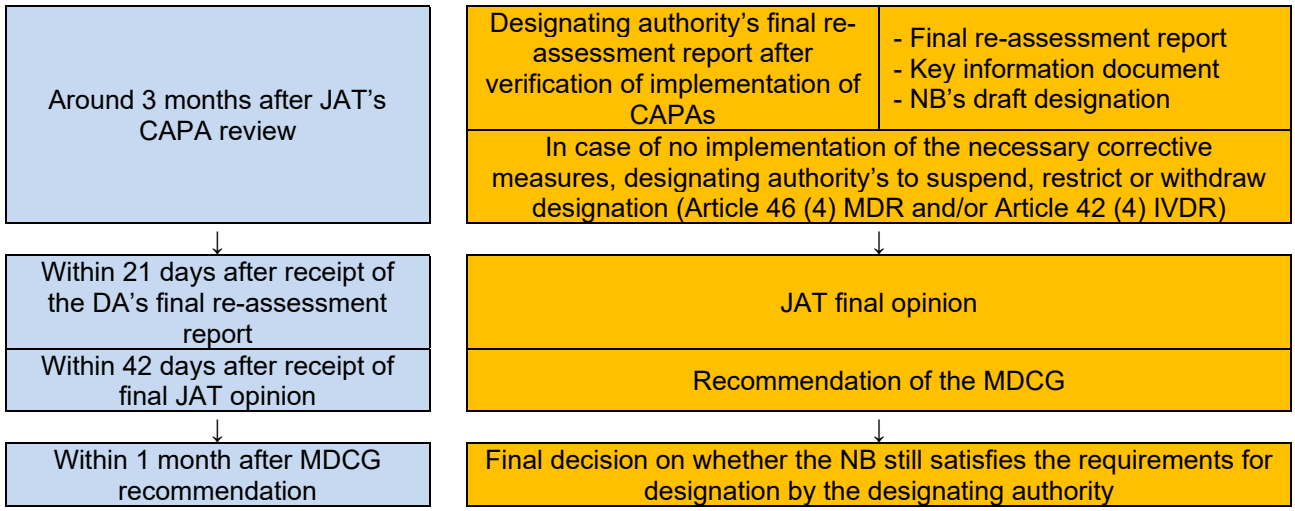
Tentative time-line	Activity	Tentative calendar (see section 2)
	Application sent to the designating authority from the CAB	Date Application Sent (DAS): e.g. 27 November 2021
Within 30 days of receipt of the application	Completeness check of application by the designating authority	DAS + 1 month e.g. 27 December 2021
Immediately after application is considered complete	Transmission of application to DG SANTE	DAS + 1 month e.g. 27 December 2021
Estimate: within 3 months after application is considered complete	Assessment of CAB's application by the designating authority and issuing of preliminary assessment report	DAS + 4 months e.g. 27 March 2022
Within 14 days after receipt of preliminary assessment report	Appointment of the JAT and scheduling of the on-site assessment	DAS + 4,5 months e.g. 10 April 2022
Within 90 days after appointment of the JAT	Formal announcement of any arrangement of practicalities for the on-site assessment Dissemination of information to JAT members Assessment of CAB application by the JAT	DAS + 7,5 months e.g. 10 July 2022
At least 2 weeks *before* the anticipated on-site assessment	Coordination teleconference between the JAT and the designating authority	DAS + 8 months e.g. 25 July 2022
On-site assessment	In accordance with the agreed assessment plan	DAS + 8,5 months e.g. 8 August 2022
Last day of the on-site assessment	Designating authority list of non-compliances and summary of the JAT assessment to be presented at the closing meeting	DAS +8,5 months e.g. 12 August 2022
Timeframe defined by the designating authority, ideally no later than 3 months after the on-site.	CAB's submission of the CAPA plan	DAS + 11.5 months e.g. 12 November 2022
Within 30 days after the on-site assessment	JAT summary assessment and any remaining diverging opinions to be sent to the designating authority	DAS + 9,5 months e.g. 12 September 2022


Estimate: Within 20 working days after receipt of CAPA plan from the CAB
Designating authority's confirmation and assessment of CAB's CAPA plan. To be forwarded to the JAT
DAS + 12.5 months
e.g. 12 December 2022
Within 40 working days after receipt of CAPA plan and the designating authority opinion
JAT assessment of CAPA plan and designating authority's opinion thereon. If applicable, request for modifications or clarifications
DAS + 14.5 months
e.g. 12 February2022
Estimate: around 6 months after receipt of CAPA plan
Designating authority final assessment report after verification of implementation of CAPAs
DAS + 17,5 months
e.g. 14 May 2023
Within 21 days after receipt of the designating authority final assessment report
JAT final opinion
DAS + 18,25 months
e.g. 5 June 2023
Within 42 days after receipt of final JAT opinion
Recommendation of the MDCG on designation
DAS + 19,5 months
e.g. 17 July 2023
Undefined
Final decision on designation by the designating authority
DAS + 20 months
e.g. 26 July 2023
Notification process

Annex 2: Flowchart of activities and times: Re-assessments

Tentative time-line	Activity
No later than 6 months before re-assessment due date	NB's documentation for re-assessment submitted to designating authority
Within 30 days of receipt of the documentation	Designating authority's check of NB's documentation for re-assessment for completeness
Within 3 months of receipt of the documentation.	Review of the documentation for re-assessment by the designating authority and issuing of PRAR
Immediately after documentation is considered complete or 1 month before re-assessment due date	Transmission of the documentation for re-assessment and PRAR to DG SANTE
Within 14 days after receipt of PRAR	Appointment of the JAT and scheduling of the on-site re-assessment
Within 90 days after appointment of the JAT	Formal announcement and arrangement of practicalities for the on-site re-assessment Dissemination of information to JAT members Assessment of NB's documentation for re-assessment by the JAT
2 weeks before the on-site re-assessment	Coordination teleconference between the JAT and the designating authority
Re-assessment due date (3 years after notification and every fourth year thereafter)	On-site re-assessment
Last day of the on-site re-assessment	Designating authority's list of non-compliances and summary of JAT assessment to be presented at the closing meeting
Within 30 days after the on-site	JAT remaining diverging opinions to be sent to the designating authority
Within 3 months[49] after the on-site re-assessment.	NB's submission of the CAPA plan
Within 20 working days after receipt of the NB's CAPA Plan	Designating authority's assessment of NB's CAPA plan. To be forwarded to the JAT
Within 40 working days after receipt of CAPA plan and the DA's opinion	JAT review of the CAPA plan and designating authority's opinion thereon. If applicable, request for modifications or clarifications

[49] If applicable, more time may be agreed between the designating authority and the NB in order to provide clarifications or modifications of the CAPA plan


Around 3 months after JAT's CAPA review
Designating authority's final re-assessment report after verification of implementation of CAPAs
- Final re-assessment report
- Key information document
- NB's draft designation
In case of no implementation of the necessary corrective measures, designating authority's to suspend, restrict or withdraw designation (Article 46 (4) MDR and/or Article 42 (4) IVDR)
Within 21 days after receipt of the DA's final re-assessment report
JAT final opinion
Within 42 days after receipt of final JAT opinion
Recommendation of the MDCG
Within 1 month after MDCG recommendation
Final decision on whether the NB still satisfies the requirements for designation by the designating authority