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| **Team NB Position in Response to MDCG 2022-14 Item Number 17 – ‘Certificates under Conditions’** |

##  Scope

This position paper considers point 17 raised within MDCG 2022-14. The point mentioned in MDCG 2022-14 is not to be specifically addressed by notified bodies, but this paper provides the position of Team NB in relation to certificates under conditions (point 17).

## In relation to point 17, what are ‘certificates under conditions’ ?

There are no specific references to ‘*certificates under conditions*’, ‘*conditional certification*‘ or ‘*provisional certification*’ within the EU Medical Device Regulation (MDR 2017/745). However, the MDR describes the potential of notified bodies issuing a certificate with specific conditions or provisions/limitations. Annex VII section 4.8, *Decisions and Certifications,* provides the following information in relation the notified body’s decision making and issuing of a certificate with conditions, limitations or provisions :

*The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, restriction and withdrawal of certificates. Those procedures shall include the notification requirements laid down in Chapter V of this Regulation. The procedures shall allow the notified body in question to:*

* (Indent 4) *decide whether* ***specific conditions or provisions*** *need to be defined for the certification,*
* (Indent 8) *issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII for a period of validity not exceeding five years and shall indicate whether there are* ***specific conditions or limitations associated with the certification,***

Team NB interprets the issuance of certificates with specific conditions as those certificates issued in exceptional circumstances and/or when specific additional activities/limitations/restrictions are to be placed on the devices to ensure a controlled release of the devices covered by those certificates. This is further clarified in article 56 (3) of the MDR;

*Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or require manufacturers to undertake specific PMCF studies pursuant to Part B of Annex XIV.*

Some stakeholders have interpreted point #17 as NBs being encouraged to issue conditional certificates or provisional certificates based on just applications received or conformity assessments being partially completed and for the NBs to complete the rest of the conformity assessment after the certificates have been issued.

Team NB does not consider the issuance of certificates under conditions as a ‘*routine*’ mechanism to allow the release of certificates without fully verifying compliance to all the applicable requirements of MDR. Such a process does not align with the aim of MDR to ensure “high level of protection of health for patients and users” and could undermine patient safety.

## Have any members of Team NB issued any *certificates under conditions*?

Under the Active Implantable/Medical Device Directives (AIMDD/MDD) there were rare occasions that certificates were issued by notified bodies with specific conditions. Some examples of certificates with conditions included:

* Limiting high risk novel technology to restricted controlled release through PMCF study release only
* Increase of specific surveillance activities for devices identified where there may be unanswered questions associated with long term safety and performance data.

## What are the concerns of Team NB for issuing certificates under conditions on a routine basis without completing the due conformity assessments?

The primary purpose of the MDR is to strengthen the safety and performance requirements to enhance patient safety and to ensure that only safe and effective medical devices are placed on the market (or put into service) for healthcare professionals, users and patients of the European Union. The MDR is clear that manufacturers need to demonstrate compliance to applicable requirements including the general safety and performance requirements prior to devices being placed on the market or put into service.

Issuing certificates with conditions without performing all the due conformity assessments, and to their full extent, could mean that devices without sufficient clinical or technical evidence are certified and placed on the market. This could compromise patient safety and is in direct conflict with the principles of MDR identified above.

It is also noted that for certain high-risk devices (class III implantable devices, Class IIb ARMS devices Rule 12), diluting the requirements on sufficient clinical evidence at the time of certification would not be aligned to the expectations of the EU Expert Panels. The Expert Panels were formed as a key part of the MDR infrastructure to ensure notified body assessments and decisions related to high-risk devices are comprehensive and are supported by sufficient clinical evidence to allow market access.

Placing conditions on certificates requires an increased level of follow-up and scrutiny by the notified body during the post market surveillance phase, ensuring the manufacturer has complied with the conditions or limitations specified on the certificates. Therefore, issuing certificates with specific conditions on a routine basis will further reduce capacity at notified bodies because of the increased burden that is associated with enhanced surveillance and closer scrutiny associated with the follow up activities.

## When do NBs consider it appropriate to issue certificates under conditions?

As described earlier in this position paper, team NB understands that there will be occasions when certificates are issued under conditions and such conditions should be limited to when the notified body needs to have reassurance around the release of a medical device on to the market.

This would include for devices that are completely novel with a high-risk profile or very innovative designs that need to have longer term clinical data to support that cannot be generated efficiently in the pre-market phase and hence can be collected during the post-market phase under specified conditions. In addition certificates could be for situations where the NB would like to closely monitor the post-market performance of a device.

Team NB also considers that a safer approach to issuing certificates with specific conditions is rather to allow for notified bodies to engage further in structured dialogue with manufacturers prior and during a conformity assessment to ensure the expectations of the notified body are aligned with the manufacturer. This will ensure that any deficiencies are appropriately addressed before or during a conformity assessment, rather than issuing certificates with gaps in data and deficiencies being resolved in the post market phase.

MDCG 2022-14 does suggest under item 15 the possibility of notified bodies holding ‘structured dialogue’ with manufacturers:

*The MDCG encourages notified bodies and manufacturers to* ***organise structured dialogues*** *before and during the conformity assessment process aimed at regulatory procedures where this is useful to enhance the efficiency and predictability of the conformity assessment process, while respecting the independence and impartiality of the notified body. Such dialogues should not be considered consultancy service7 . [actors: MDCG, NBO]*

## What are the next steps in relation to point 17 of MDCG guidance 2022-14 issued by the European Commission?

MDCG 2022-14, point 17 highlights that the MDCG Clinical Investigation and Evaluation (CIE) working group at the European Commission will provide further guidance around conditional certification.

Team NB with other Notified bodies look forward to collaborating with the EU Commission and NBO on developing further guidance on defining the scenarios when certificates with conditions may be issued