MDCG 2019-10 rev. 1

Application of transitional provisions concerning validity of certificates issued in accordance to Directives 90/385/EEC and 93/42/EEC

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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.

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MDCG 2019-10 revision 1 changes
MDR postponement dates: from 2020 to 2021

Application of transitional provisions concerning validity of certificates issued in accordance to Directives 90/385/EEC and 93/42/EEC[1]

According to Article 120(2) of Regulation (EU) 2017/475 on Medical Devices (the MDR), certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC (the Directives) will remain valid until 26 May 2024 at the latest. However, Article 120(3) establishes specific conditions that such certificates, and the related devices thereof, have to comply with. In particular, it is required that the notified body that issued the certificate – under a valid designation – continues to be responsible for the appropriate surveillance activities with respect to all of the applicable requirements related to the devices it has certified and that it has the possibility to take any necessary measure in relation to those.

It has to be noted that, as reported in FAQ n.17 of the MDR transitional provision document published by the CAMD Transition Sub Group, the contract between the manufacturer and the notified body who issued the certificate under the relevant Directive shall include provisions allowing the appropriate performance of such surveillance activities.

In order to allow manufacturers to take advantage of Art. 120(2) and Art. 120(3) of the MDR, it needs to be ensured that Authorities responsible for notified bodies have the right to and do monitor those notified body's activities to the extent appropriate and necessary. For this purpose, Article 120(3) and Article 122(1) of the MDR provide the necessary legal basis for Member States to establish the necessary legal empowerments[2] by means of National law to carry out the needed monitoring activities in relation to Notified Bodies. All this is regardless of whether the Notified Body has applied or not to be designated under the MDR and/or it has a still valid designation under the Directives during the validity of certificates issued in accordance to the Directives.

Concerning information published in the NANDO database, in accordance to Article 120(1) of the MDR, any publication of a notification in respect of a notified body in accordance with the Directives will become void as from 26 May 2021. Therefore, NANDO will only be used in relation to the

Directives for information purposes after 25 May 2021. NANDO will therefore list those notified bodies that have been designated under the Directives with a clear message that they are not able to issue new certificates but only allowed to carry out surveillance activities for valid certificates in the transitional period, as established in Article 120 of the MDR.

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1 This document specifically refers to transitional provisions laid down in Regulation (EU) 2017/745 but can be applied by analogy to Regulation (EU) 2017/746.

2 It should be noted that relevant legal empowerments might be already available by means of National law which build on different EU pieces of legislation.