MDCG 2018-8

Guidance on content of the certificates, voluntary certificate transfers

November 2018

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.

In the meeting of 30 November 2018, MDCG endorsed the below positions. These positions will be part of a more comprehensive guideline related to notified bodies, currently under development.

Content of the certificate under MDR / IVDR Annex XII, Chapter II, section 10

Certificates do not need to include reference to relevant common specifications or harmonised standards as long as such information on all examinations and tests performed is traceable and available from e.g. report(s) which are mentioned in the certificate.

Voluntary certificate transfer under MDR Article 58 / IVDR Article 53

While MDR Article 58(1) / IVDR Article 53(1) sets out the requirements for a transfer agreement, it does not specify the conformity assessment activities to be performed by the incoming NB. The incoming NB may decide not to carry out full conformity assessment activities according to Article 52 MDR / Article 48 IVDR, as long as it does have sufficient information in respect to the conformity activities performed by the outgoing NB.

For quality management system certificates, the incoming NB needs to perform appropriate on-site audit(s) and assessments to ensure that the manufacturer in question applies the approved QMS and the post-market surveillance plan prior to the issue of any certificate. In respect to the assessment of technical documentations on a sampling basis, the oncoming NB shall review the previous assessment results together with a sample of a technical documentation and draw up or amend a sampling plan. For product certificates (Annex IX Chapter II/Annex X), new certificates without a comprehensive (initial) review may be issued as long as the documentation received does not identify ongoing existing or other concerns.

The incoming NB assumes full responsibility for the new certificates issued following the transfer.