

The general process of medical device CE marking

Certification and procedures often follow a certain pattern, the minimum requirement for CE marking is through the self-certification process (Class I devices). Even if a Notified Body was involved or not, every manufacturer has to fulfil both the essential requirements in accordance with Annex 1 and every manufacturer has to complete a Declaration of Conformity in accordance with Annex VII.

Manufacturers that are not situated in the EU have to apply for CE marking via an Authorised Representative in accordance with Article 14.2 of the Medical Device Directive (93/42/EEC) + IVD Directive (98/79/EC, Article 1 §29). The registration is performed using the DIMDI (German Institute for Medical Documentation and Information) databank system. This databank can only be used by Authorised Representatives or by manufacturers that have a registered place of business in the EU. The DIMDI databank system is using similar to the Universal Medical Device Nomenclature System (UMDNS), which provides a common basis for device classification.

One additional problem is that registered trade names and trade marks might not be accepted in a different country, for example CE Marking in the US it is not going to necessarily be recognised in the EU. Larger manufacturers are rarely asked to provide their European distributors or end users with proof of CE compliance, they are seldom called upon to provide evidence of registration, however smaller manufacturers that work via an Authorised Representative are required to provide this evidence.

The DIMDI database is not the only hurdle that manufacturers have to get across, after they have successfully completed a suitable conformity assessment procedure in accordance with the relevant directives, the manufacturer must then gather the various directives, standards and guidance documents needed to demonstrate compliance.

Final compliance with the directives does not mean that the finishing line has been crossed. Standards are revised constantly and those manufacturers who do not actively take part in these revisions will find it impossible to keep up to date.

Small overseas companies manufacture a large percentage of medical devices; if competent authorities fail to understand the unique needs of these manufacturers there is the possibility that an important source of medical supplies will be lost.