FAQs

What is an accessory to a medical device?
An article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

What is a CE Mark?
The CE mark that appears on a medical device or on its packaging means that the device satisfies the relevant essential requirements and is fit for its intended purpose as specified by the manufacturer. All medical devices, (except custom-made devices and those intended for clinical investigations) must bear a CE mark.

What is a class I medical device manufacturer?
Any person who manufactures, for the purpose of placing on the market, a medical device that is classified as a class I device according to the medical devices directive. Class I devices are deemed to carry the lowest risk and so class I manufacturers self-declare conformity with the medical devices directive.

What is conformity assessment for medical devices?
Conformity assessment is the process of demonstrating a medical devices compliance with the Requirements of the relevant Directive. How conformity is demonstrated varies according to the class of the device. All devices except class I medical devices (non-sterile/no measuring function) must undergo conformity assessment by a notified body for medical devices

What is a Conformity Assessment Body for medical devices?
Conformity assessments for medical devices are conducted, when required, by conformity assessment bodies that have been specifically notified to the Commission i.e. notified bodies. Notified bodies are designated by a designating authority to carry out conformity assessments to the Medical Device, AIMD or IVD directive
The activities carried out by notified bodies include reviewing technical files and design dossiers for devices, auditing manufacturing facilities and products, assessing changes, issuing, suspending or withdrawing certificates, and conducting manufacturer/product reviews/audits on an ongoing basis.

Medical device manufacturers can chose any notified body to conduct a conformity assessment of a medical device provided that the device is within the scope of designation.

What is a custom-made medical device manufacturer?
A person who specifically makes any device in accordance with a duly qualified

Practitioner's written prescription which gives, under their responsibility, specific design characteristics and is intended for sole use of a particular patient.

The prescription for a custom made device must be completed by a person authorized by virtue of their professional qualifications to do so.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom-made devices.

What is an importer of a medical device?

An importer (a person responsible for placing on the market) is any natural or legal person established in the Community who places a product from a third country on the Community market.

What does the term 'intended purpose' mean in relation to a medical device?

The use for which the device is intended according to the data supplied by the manufacturer on the labeling, in the instructions and/or in promotional materials

What is a Notified Body?

Notified Bodies are part of the regulatory system established by the Medical Device Directives. They are usually certification bodies with relevant expertise that are responsible for ensuring that the conformity assessment procedures are followed by the manufacturer as well as establishing that devices conform to the relevant essential requirements of the Directives and also to established standards in design and production. Such bodies may be privately or state owned and must be notified formally to the European Commission for the purposes of the Directives by their relevant CA once they have demonstrated that they have met the criteria set out in the annexes to the Directives. They issue the approval to the CE marking of conforming medical devices and they may be notified for some or all of the conformity assessment procedures described in the annexes.