



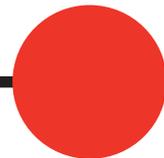
...making excellence a habit.™

Want to know more about the Notified Body?

Everything you need to know to help you through the Notified Body process and on to accreditation.

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We are a respected, world-class Notified Body dedicated to providing rigorous regulatory and quality management reviews and product certifications for medical device manufacturers — around the world. For more than 100 years, BSI's expertise has provided an assurance of safety and quality to manufacturers in over 150 countries.

Meet the world with confidence

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, predictable conformity assessments, evaluations and certifications.

The challenges medical device manufacturers face in today's highly competitive marketplace make it essential to ensure that your product meets all regulatory and quality requirements before launch. It is critical to work with a leader who understands the industry and has the experience to review and confirm the products' readiness for market — efficiently, reliably and promptly. BSI is a company that has been leading the way in assisting manufacturers to navigate through the maze of regulatory requirements.

While every effort has gone into this booklet to ensure that it accurately reflects the regulatory environment at the time of publication, you should be aware that this is complex and can change. Therefore, this booklet is not to be considered as providing any legal advice and is not to be used as a substitute to reading the regulations directly or seeking advice from a qualified expert.

Welcome to your personal guide to the notified body.

What is CE marking?

CE marking is the medical device manufacturer's claim that a product meets the essential requirements of all relevant European Directives and is a legal requirement to place a device on the market in the European Union.

The three medical devices Directives are:

- Medical Devices Directive (MDD)
- Active Implantable Medical Devices Directive (AIMDD)
- In Vitro Diagnostics Directive (IVDD)

The EU is currently reviewing all three Medical Device Directives.

There are a number of other related Directives and Regulations that might need to be considered for example, Regulation 722/2012 concerning active implantable medical devices and medical devices manufactured utilising tissues of animal origin. This document is to provide a basic overview and so does not include every necessary detail for your product.

EU Directives lay down certain end results that must be achieved in every Member State. National authorities have to adapt their laws to meet these goals, but are free to decide how to do so. **Regulations** are the most direct form of EU law - as soon as they are passed, they have binding legal force throughout every Member State, on a par with national laws. National governments do not take action themselves to implement EU regulations, but do ensure their national law does not define the subject matter any further.

Where does the CE mark apply?

The **CE** mark is applicable in the countries of the "European Economic Area".

This includes:

- The 28 Member States of the EU plus: Iceland, Liechtenstein, Norway, Switzerland and Turkey.

IMPORTANT!
No medical device can be placed on the market within Europe without a CE mark to one of the three medical device Directives, even if the product is manufactured outside the EU.

You can take your device to market anywhere in the "European Economic Area"

What is the role of the Competent Authority?

Each country within the EU and partner countries has a Competent Authority. The Competent Authority is a body within the government of the Member States that transposes the requirements of the Medical Device Directives into National Law.

The Competent Authority is also responsible for specifying one or more Notified Bodies, to act as independent third party assessors of the manufacturer's compliance.

Competent Authorities ensure that EU Directives are set (legally called Transposed) into each Country's Law.

The Competent Authority in the UK is the Medicines and Healthcare Products Regulatory Agency (MHRA).

What is the role of the Notified Body?

The role of a Notified Body is to conduct a conformity assessment under the relevant EU Directives. The Notified Body conducts the conformity assessment against the relevant sections of the applicable Directive (MDD, AIMDD or IVDD). The conformity assessment usually involves an audit of the manufacturer's quality system and depending upon the particular classification of the device, a review of the relevant technical documentation provided by the manufacturer in support of the safety and performance claims for the device. The technical documentation is assessed against the essential requirements set out within the EU Directives and considers the relevant guidance set out by the EU.

Once the Notified Body has determined a manufacturer has conformed to the relevant assessment criteria, it issues a CE certificate to show that the products assessed meet the requirements.

The manufacturer signs a Declaration of Conformity and applies the CE mark (with or without the Notified Body number).

IMPORTANT!
"The Notified Body and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications".

Manufacturers are free to choose a suitable Notified Body – ensuring that they are qualified and experienced with the product to be certified.

How many Notified Bodies are there for the CE mark?

There are over 70 EU Notified Bodies in total that can certify to the Medical Device Directives. However, not all of these Notified Bodies can certify to all categories of medical device products. Products holding a CE mark from any of the seventy plus Notified Bodies can be marketed to patients, pharmacies, clinicians and other healthcare professionals in any EU country.

Nando

Visit the Nando Website to see the accurate list of designated Notified Bodies:
ec.europa.eu/enterprise/newapproach/nando/

How many Medical Device Directives are there?

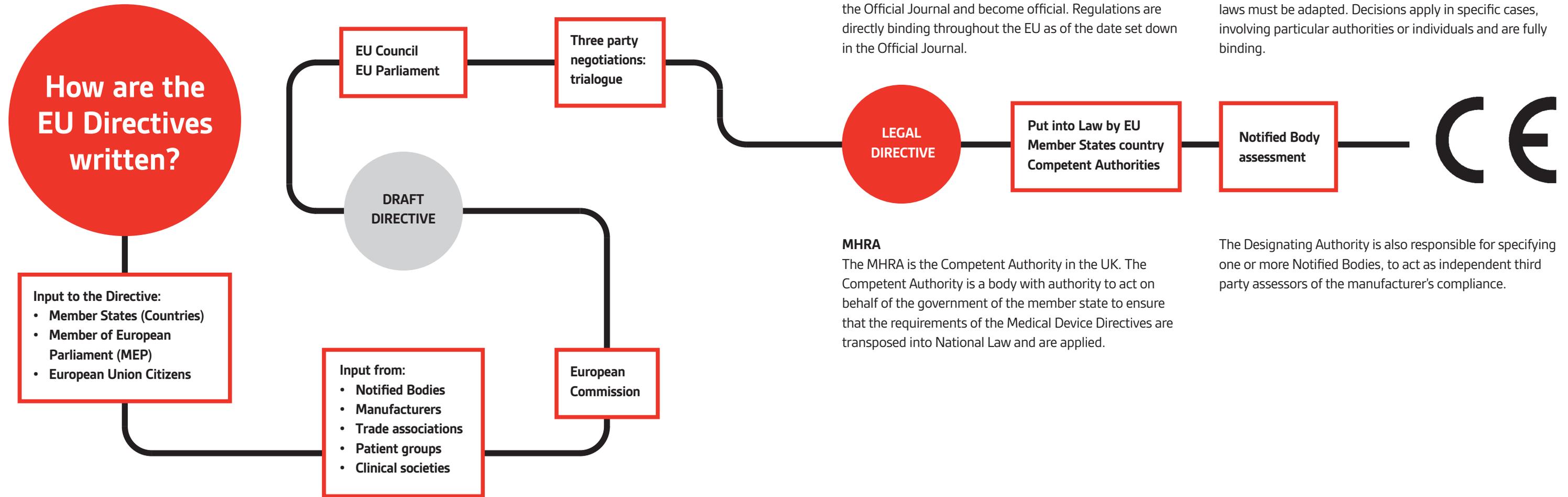
There are three Medical Devices Directives

The three Medical Devices Directives are:

- Medical Devices Directive (MDD)
- Active Implantable Medical Devices Directive (AIMDD)
- In Vitro Diagnostics Directive (IVDD)

The EU is currently reviewing all three Medical Device Directives.

Who decides on the content of the Directives?



Legal Directive

Once both European Parliament and Council have approved the final text of a legislative proposal, it is jointly signed by the Presidents and Secretaries General of both institutions. After signature, the texts are published in the Official Journal and become official. Regulations are directly binding throughout the EU as of the date set down in the Official Journal.

Directives lay down end results to be achieved in every member state, but leaves it up to national governments to decide how to adapt their laws to achieve these goals. Each Directive specifies the date by which the national laws must be adapted. Decisions apply in specific cases, involving particular authorities or individuals and are fully binding.

MHRA

The MHRA is the Competent Authority in the UK. The Competent Authority is a body with authority to act on behalf of the government of the member state to ensure that the requirements of the Medical Device Directives are transposed into National Law and are applied.

The Designating Authority is also responsible for specifying one or more Notified Bodies, to act as independent third party assessors of the manufacturer's compliance.

What is the process a manufacturer has to go through to get a CE mark?

MDD and AIMD

The route to follow for certification depends on the risk classification of the device.

- For Low risk Class I devices the manufacturers self certify's, applying the CE mark. If the device has a measuring capability or is supplied sterile a Notified Body is however required.
- For Class IIa (low to medium risk), Class IIb (medium to high risk) and Class III (high risk) devices, a Notified Body audits the manufacturer's quality system and the manufacturer requires a favourable audit to proceed to CE marking.
- For Class III devices a Notified Body evaluates the design of the medical device, by reviewing a design dossier submitted by the manufacturer, and issues a certificate of conformity with the Directive if it is satisfied with the device's safety and performance data.
- AIMD, Active Implantable Medical Devices are regarded, by their very nature, as high risk devices in terms of the AIMDD (90/385/EEC) and must undergo Full Quality Assurance including design of the product and post market surveillance.

Device classification examples

Class	Device Examples
I (low risk)	<ul style="list-style-type: none"> • Bandages • Wheelchairs • Corrective glasses and frames
IIa (low to medium risk)	<ul style="list-style-type: none"> • Disposable contact lenses • Suture • Dental fillings
IIb (medium to high risk)	<ul style="list-style-type: none"> • Complex wound dressings for burns • Baby incubators • Dialysis equipment
III (high risk)	<ul style="list-style-type: none"> • Hip replacements • Drug eluting stent • Absorbable sutures
AIMD	<ul style="list-style-type: none"> • Implanted cardiac pacemakers

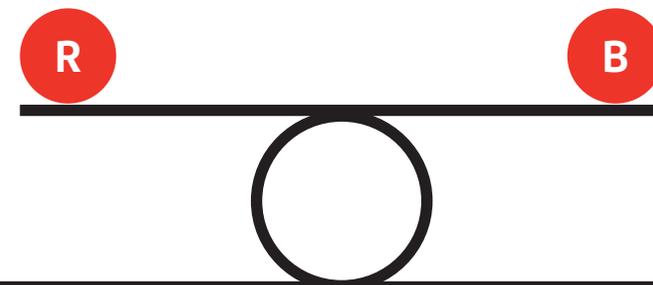
This chart shows examples of products that fall into each class of risk.

In Vitro Diagnostic products

IVDs are medical devices and accessories used to perform tests on samples, such as blood, urine, tissue, effectively any sample which can be taken away from the human body to help detect infection, diagnose a medical condition, prevent disease or monitor drug therapies.

The Directive groups IVDs into four categories according to the perceived risk associated with the relative hazard to public health and/or patient treatment by an IVD failing to perform as intended.

- R** = Risk
- B** = Benefit



It's all about the risk versus benefit balancing act.

IVD classification examples

IVD Classification		Examples
General	No Notified Body required Manufacturer self declares	Tests for Hormones, Cardiac Markers, Hematology and Clinical Chemistry Tests
Self Test	Notified Body required Review of design & labeling for lay user suitability	Pregnancy, Cholesterol Home Tests
Annex II List B	Notified Body required Audit of technical documentation & quality management system	Rubella, PSA, Self Test for Blood Glucose
Annex II List A	Notified Body required Design Dossier Review (Including Compliance to the CTS) Audit of quality management system Batches released by the Notified Body	HIV, Hepatitis ABO Blood Grouping

Definition of an audit
An official inspection of an individual's or organization's accounts, typically by an independent body.

What does a Notified Body have to review as part of the assessment process?

From an EU regulatory perspective there are key requirements to meet, these are contained in the three EU Medical Device Directives (MDD, AIMDD and IVDD). The conformity assessment requires an audit to be carried out on-site of the manufacturer's quality system or evidence of a current valid QMS certificate (see below) from a recognised Notified Body.

**Congratulations
your product
has passed.**

The CE process includes a Quality Management System (QMS) assessment. A comprehensive audit of the facility includes, reviewing the manufacturing process, systems, controls, material handling, microbiological & sterile systems etc. The audit is carried out to the standard ISO 13485 (the harmonized Medical Device QMS standard) and has a three year validity; as part of this process there is an annual surveillance audit to ensure conformity is maintained.

Dependent on the particular classification of the device, a Notified Body will carry out either a full technical file review or in the case of Class III/AIMD/Annex II List A, an in-depth design dossier review (Risk based and defined within the Directives). The manufacturer must provide all the technical documentation in support of the safety and performance claims for the device. Technical documentation is assessed against the essential requirements set out within the EU Directives; it considers the standards, common technical specifications, and relevant guidance set out by the EU.

ISO 13485

The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a quality management system. Adopting ISO 13485 provides a practical foundation for manufacturers to address the regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices.

Does a Notified Body have to see the product as part of the **certification** process?

There are a number of conformity assessment procedures that a manufacturer can follow to **CE** mark a medical device. The **CE** process involves a Quality Management System (QMS) assessment that reviews the design, manufacture, inspection and test processes during which there will be direct involvement with the product.

For IVDs Manufacturers with Annex II List A devices are required to have every batch of device released by the Notified Body which may often require testing of the product.

Quality Management System (QMS)

Conformity Assessment Route

Faults and alterations

When a product component is altered, who needs to do what?

It is the responsibility of the manufacturer to inform the Notified Body of any changes to a medical device, and demonstrate to the Notified Body that the changes do not adversely affect the device's safety and performance. The Notified Body reviews the submitted data against the 'Essential Requirements' of the relevant medical device Directive to ensure conformity and to confirm the certificate remains valid. There are different requirements placed on devices dependent on its conformity assessment route.

IMPORTANT!

The entry of data onto the European Data Bank (EUDAMED) is the responsibility of the Competent Authority of each member state.

Who is responsible for monitoring and reporting product faults once they have been released onto the market?

Once a product is commercialised, it is for the manufacturer to report adverse events and product performance issues to the Competent Authority. The Competent Authority is required to react and respond appropriately in the interests of patient safety. The relevant Competent Authority in a given EEA member state will co-ordinate the reported events under the EU vigilance system and, where appropriate, share this information and any field safety actions with other member states.

Unannounced audits

Notified Bodies are required under EU legislation to perform unannounced audits of medical device manufacturers and related suppliers. Key requirements from this section of the Commission Recommendation include the following requirements:

- Unannounced audits of the manufacturer or one of its critical subcontractors or suppliers of crucial components.
- The unannounced audit must be additional to the regular assessment cycle and at least one day by two auditors.
- At least one unannounced audit per 3rd year with increased frequency for high risk device manufacturers and/or manufacturers with a poor history of compliance, or where specific information provides reasons to suspect non-conformities of the devices or their manufacturer.
- Specified areas of focus for the visit. These include manufacturing, testing, linkage of manufactured items to the technical file and device specifications, identification and traceability, reconciliation of materials and critical processes, plus further testing of devices with a design or type examination certificate.

No prior warning will be given of unannounced audits

What a Notified Body does NOT do

The directors, executives and personnel (whether directly employed or subcontracted) responsible for carrying out the evaluation and verification activities shall be independent of both the manufacturers for whom the Notified Body conducts assessments and the commercial competitors of those manufacturers, during their employment by the Notified Body. Personnel shall not have been involved in the design, construction, marketing or maintenance of the devices.

Define the Directives

The Notified Body does not write or decide on the EU regulations – their input will be considered during the debating stage shown above but they will not decide on the legislation. Notified Bodies assess against the requirements of the Directives, they do not write them.

Consultancy

Notified Body personnel (whether directly employed or subcontracted) shall not offer or provide (or have offered or provided) consultancy or advice to the manufacturer, the authorised representative, a supplier or their commercial competitor as regards the design, construction, marketing or maintenance of the products under assessment.

Further information

Further information may be found on the following websites:

- **European Commission Health Devices**
ec.europa.eu/health/medical-devices
- **Full list of Notified Bodies and Competent Authorities**
ec.europa.eu/enterprise/newapproach/nando/
- **MHRA**
www.mhra.gov.uk/
- **ZLG**
www.zlg.de/en/zlg.html
- **Notified Body Operations Group (NBOG)**
www.nbog.eu/
- **Team-NB – Association of medical Notified Bodies**
www.team-nb.org/

Where can I find a full list of Notified Bodies?

The BSI Medical Device Mission

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, predictable conformity assessments, evaluations, and certifications.

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