

**Want to
know more
about the
Notified
Body?**

**Everything
you need to
know about Notified
Body certification to
the Medical Devices
Directives and
Regulations**

Contents

- 3** Meet the world with confidence
- 4** What is **CE** marking?
- 5** Where does the **CE** mark apply?
- 6** What is the role of the Competent Authority?
- 7** What is the role of the Notified Body?
- 8** How many Notified Bodies are there for the **CE** mark?
- 9** How many Medical Devices Directives and Regulations are there?
- 10** Who decided on the content of the new Regulations?
- 12** What is the process a manufacturer has to go through to get a **CE** mark?
- 14** In Vitro Diagnostic products
- 16** What does a Notified Body have to review as part of the assessment process?
- 18** Does a Notified Body have to see the product as part of the certification process?
- 19** Faults and alterations
- 20** Unannounced Audits
- 21** What a Notified Body does **NOT** do
- 22** Further Information
- 23** The BSI Medical Device Mission

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 190 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 providing robust product and system certification that inspires confidence and stands up to scrutiny.

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 legislation directly or seeking advice from an independent, 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 requirements of all relevant European Directives and Regulations 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 Directives will be replaced by the Medical Devices and IVD Regulations on 26 May 2020 and 26 May 2022, respectively. After these dates, no new Directive certificate can be issued, and current certificates will have limited validity, as described in the Regulation articles on transitional provisions.

The new Regulations are:

- Regulation (EU) 2017/745 Medical Devices Regulation (MDR), replacing MDD and AIMDD
- Regulation (EU) 2017/746 In Vitro Diagnostic Regulation (IVDR), replacing IVDD

There are a number of other related Directives and Regulations that might need to be considered for example, Regulation 722/2012 concerning devices manufactured utilizing 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 (EEA) - i.e. All EU member states plus Iceland, Liechtenstein and Norway
- Switzerland
- Turkey

IMPORTANT!

No medical device can be placed on the market within Europe without a CE mark to one of the Medical Devices Directives or Regulations, 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, and is responsible for ensuring law of the Regulation within their country.

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.

The Competent Authority in the UK is the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Competent Authority in The Netherlands is the Ministry of Health, Welfare and Sport (VWS).

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 or Regulations. 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 or the General Safety and Performance Requirements (GSPRs) within the EU Regulations, 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. They 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 50 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 designated Notified Bodies can be marketed to patients, pharmacies, clinicians and other healthcare professionals in any EU country.

Notified Bodies that have applied for designation under the Regulations are now undergoing designation assessments. Keep up to date with the latest developments by visiting our transition web pages:

- MDR: bsigroup.com/MDR-Revision
- IVDR: bsigroup.com/IVDR-Revision

Nando

Visit the Nando Website to see the accurate list of designated Notified Bodies:
<http://ec.europa.eu/growth/tools-databases/nando/index.cfm>

How many Medical Devices Directives and Regulations are there?

The three Medical Devices Directives are:

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

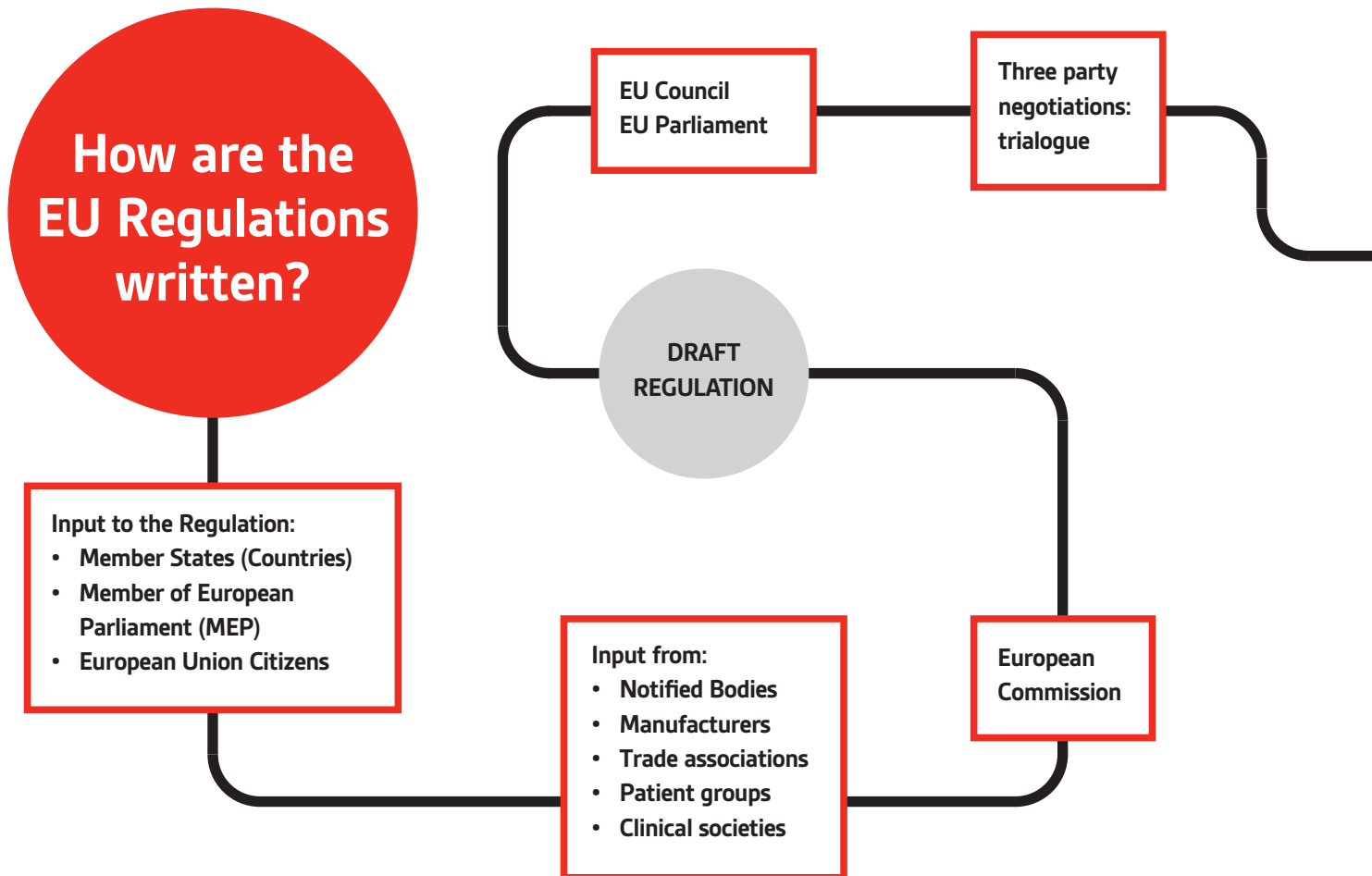
The Directives will be replaced by the Medical Devices and IVD Regulations on 26 May 2020 and 26 May 2022, respectively. The new Regulations are:

- Regulation (EU) 2017/745 Medical Devices Regulation (MDR), replacing MDD and AIMDD
- Regulation (EU) 2017/746 In Vitro Diagnostic Regulation (IVDR), replacing IVDD



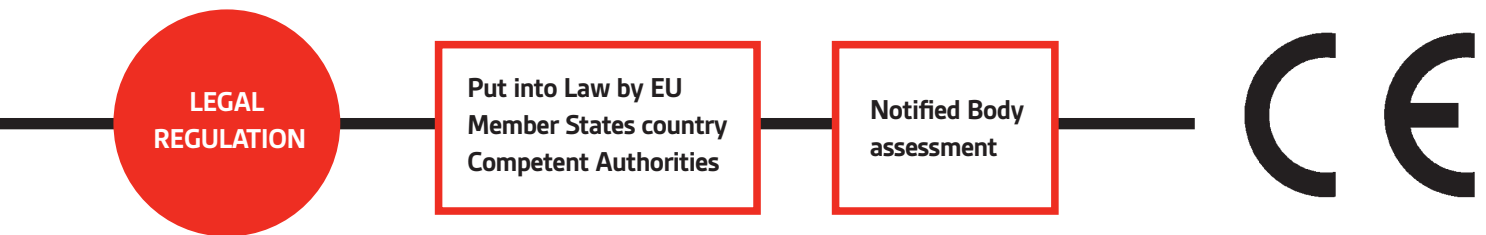
**The
Regulations
will replace the
Directives**

Who decided on the content of the new Regulations?



Legal Regulation

Regulations have been approved by European Parliament and Council for the final text of a legislative proposal, the Regulation was jointly signed by the Presidents and Secretaries General of both institutions. The regulation was 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.



Competent Authorities

The Competent Authority is a body with the authority to act on behalf of the government of the Member State to ensure the law of EU Regulations in their country. The MHRA is the Competent Authority in the UK. Ministry of Health, Welfare and Sport (VWS) is the Competent Authority in The Netherlands.

The Designating Authority is 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?

MDR

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

- For Low risk Class I devices the manufacturer self certifies, applying the CE mark. If the device has a measuring capability or is supplied sterile, a Notified Body is however required. This will include reusable Class I devices under the MDR.
- 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 the technical documentation submitted by the manufacturer, and issues a certificate of conformity with the Regulation 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. These devices will be classified as Class III devices under the MDR.

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 (Class III, high risk, under the MDR)	<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, predict a condition, prevent disease or monitor drug therapies.

IVDs are grouped 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.

The list-based product grouping used in the IVD Directive will be replaced with a rule-based classification system in the IVD Regulation, allowing devices to be more appropriately categorized into one of four risk classes.

R = Risk **B** = Benefit



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


Device classification under the IVDR

Class D	Class C	Class B	Class A
High personal risk, high public health risk	High personal risk, moderate to low public health risk	Moderate to low personal risk, low public health risk	Low personal risk, low public health risk
<ul style="list-style-type: none"> • HIV 1/2 • Hepatitis C virus • Hepatitis B virus • HTLV I/II • Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems • CHAGAS • Syphilis (used to screen blood donations) 	<ul style="list-style-type: none"> • Syphilis (diagnosis only) • Neonatal screening for metabolic disorders e.g. PKI • Rubella • Cancer test • Companion diagnostics • Blood glucose meters/strips • Blood gas analysers • Self tests 	<ul style="list-style-type: none"> • Thyroid function • Clinical chemistry • Self-test devices listed as not Class C - Pregnancy, Fertility, Cholesterol tests and detection of glucose, erythrocytes, leucocytes and bacteria in urine 	<ul style="list-style-type: none"> • Accessories • Wash buffers • Specimen receptacles • Instruments • Culture media

'Near patient tests' are classified in their own right

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 Devices Directives (MDD, AIMDD and IVDD) and the new Regulations (MDR and IVDR). The conformity assessment requires an on-site audit to be carried out of the manufacturer's quality system or evidence of a current valid QMS certificate from a recognized 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 usually carried out to the standard ISO 13485 (the Medical Device QMS standard) and the ISO 13485 Certificate has a three year validity; as part of this process there is an annual surveillance audit to ensure conformity is maintained.

Technical documentation is assessed against the requirements of the Directives or Regulations; it considers the standards, Common Specifications, and relevant guidance of the EC: European Commission (MEDDEV guidances).

The depth of the technical documentation review conducted by the Notified Body is dependent on the device's risk classification, as defined by the relevant Directive or Regulation. The manufacturer must provide all the technical documentation in support of the safety and performance claims for the device.

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 **ce** certification process?

There are a number of conformity assessment procedures under the Directives and Regulations 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.

Manufacturers of Annex II List A IVDs under the IVDD are required to have every batch of device released by the Notified Body, which may often require testing of the product. This will also apply to Class D devices, Class B-D self-tests/near patient tests, IVDs incorporating a medicinal substance or Companion Diagnostics under the IVDR.

Quality
Management
System (QMS)

Conformity
Assessment
Route

Changes and Post market experience

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

Under the Regulations, it is the responsibility of the manufacturer to inform the Notified Body of changes to a medical device, or the Quality Management System it was manufactured under. The manufacturer should 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 Safety and Performance Requirements of the relevant Regulation 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 Database of Medical Devices (EUDAMED) is the responsibility of the Competent Authorities, notified bodies, economic operators and sponsors of systems referred to in Article 33 of the MDR and Article 30 of the IVDR.

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 Corrective 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 and MDR/IVDR Annex IX 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 every 5 years, 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 or Regulations

The Notified Body does not write or decide on the EU legislation – their input will be considered during the debating stage 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**
<http://ec.europa.eu/health/medical-devices>
- **Full list of Notified Bodies and Competent Authorities**
<http://ec.europa.eu/growth/tools-databases/nando/>
- **Ministry of VWS (Health Welfare, Sport)**
www.government.nl/ministries/ministry-of-health-welfare-and-sport
- **MHRA**
www.mhra.gov.uk/
- **Notified Body Operations Group (NBOG)**
www.nbog.eu/
- **Team-NB – The European Association for Medical Devices of Notified Bodies**
www.team-nb.org/

Where can
I find a full list
of Notified
Bodies?

DISCLAIMER

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 legislation directly or seeking advice from a qualified expert.

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.



BSI Notified Body (0086)

Kitemark Court

Davy Avenue

Knowlhill

Milton Keynes

MK5 8PP

United Kingdom

T: +44 345 080 9000

E: eu.medicaldevices@bsigroup.com

W: bsigroup.com/medicaldevices

BSI Notified Body (2797)

Say Building

John M. Keynesplein 9

1066 EP Amsterdam

The Netherlands

T: +31 20 346 0780

E: eu.medicaldevices@bsigroup.com

W: bsigroup.com/nl-NL

