CE Mark and EU Medical Device Approvals

Jenny Amos
Member countries of the EU (year of entry)

The European Union has 28 member countries:

- Austria (1955)
- Belgium (1958)
- Bulgaria (2007)
- Croatia (2013)
- Cyprus (2004)
- Czech Republic (2004)
- Denmark (1973)
- Finland (1995)
- France (1958)
- Germany (1958)
- Greece (1981)
- Ireland (1973)
- Italy (1958)
- Luxembourg (1958)
- Malta (2004)
- Netherlands (1958)
- Poland (2004)
- Portugal (1986)
- Romania (2007)
- Slovakia (2004)
- Slovenia (2004)
- Spain (1986)
- Sweden (1995)
- United Kingdom (1973)

On the road to EU membership

Candidate countries

- Albania
- Montenegro
- Serbia
- The former Yugoslav Republic of Macedonia
- Turkey

Potential candidates

- Bosnia and Herzegovina
- Kosovo *
  * This designation is without prejudice to positions on status, and is in line with UNSCR 1244/99 and the ICJ Opinion on the Kosovo declaration of independence

List of EU and EFTA states

<table>
<thead>
<tr>
<th>EU countries</th>
<th>EFTA countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Italy</td>
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<tr>
<td>Belgium</td>
<td>Latvia</td>
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<td>Bulgaria</td>
<td>Lithuania</td>
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<td>Croatia*</td>
<td>Luxembourg</td>
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<tr>
<td>Cyprus</td>
<td>Malta</td>
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<td>Czech Republic</td>
<td>Netherlands</td>
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<td>Denmark</td>
<td>Poland</td>
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<td>Finland</td>
<td>Romania</td>
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<td>France</td>
<td>Slovakia</td>
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<tr>
<td>Germany</td>
<td>Slovenia</td>
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<td>Great Britain</td>
<td>Spain</td>
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<td>Greece</td>
<td>Sweden</td>
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<td>Hungary</td>
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<td>Ireland</td>
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<td>Iceland</td>
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<td>Norway</td>
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<tr>
<td>Principality of Liechtenstein</td>
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<tr>
<td>Switzerland</td>
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</tr>
</tbody>
</table>
Placing on the Market Overview

Legal Manufacturer applies CE-mark

In order to place product in EU, LM must be located in EU or designate an Authorized Representative (click me)

Register Device with Local CA

Wellkang Ltd
Suite B
29 Harley Street
LONDON, W1G 9QR
United Kingdom
## Overview of agencies involved in medical devices in EU

<table>
<thead>
<tr>
<th>Document</th>
<th>Type</th>
<th>Name</th>
<th>Creator</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIMD 90/385/EEC,</td>
<td></td>
<td></td>
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<tr>
<td>IVDD 98/79/EC</td>
<td></td>
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</tr>
<tr>
<td>MEDDEV</td>
<td>Guidance Documents</td>
<td>Medical Device</td>
<td>European Commission, industry associations, health professionals associations, NBs and European Standardisation Organisations</td>
</tr>
<tr>
<td>NBOG</td>
<td>Guideline Documents</td>
<td>NB Operations Group</td>
<td>European Commission, Member States Competent Authorities</td>
</tr>
<tr>
<td>NB-MED</td>
<td>Standards (voluntary)</td>
<td>European Association Medical devices of NBs</td>
<td>NBs: 23 members</td>
</tr>
<tr>
<td>ISO</td>
<td>Standards (voluntary)</td>
<td>International Standards</td>
<td>National Standard Bodies – world-wide</td>
</tr>
<tr>
<td>CEN</td>
<td>Standards (voluntary)</td>
<td>European Committee for Standardization</td>
<td>National Standard Bodies – EU</td>
</tr>
</tbody>
</table>
MDD, Medical Device Directive 93/42/EEC

Definitions of
• medical devices
• accessories
• Custom-made devices
• device intended for clinical investigation

are listed in the Intro to Medical Devices course
MEDDEV

• guidance documents assist stakeholders in implementing directives related to MDs

• promotes a common approach to be followed by manufacturers and NBs that are involved in conformity assessment procedures

• accordance with the directives

• not legally binding. However, it is expected that the guidelines be followed, ensuring the uniform application of relevant directive provisions.

• http://ec.europa.eu/growth/sectors/medical-devices/guidance_en
EU MDD Classifications

Applicable:
• MDD 93/42/EEC
• AIMD 90/385/EEC
• IVDD 98/79/EC

EU MDD Classifications:
• Class I (sterile, measuring function)
• Class IIa
• Class IIb
• Class III

Annex IX, MDD 93/42/EEC
EU has 3 classes but many special cases within each...
AIMD, Active Implantable Medical Device Directive, 90/385/EEC

- "any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure". Also apply to any accessories that are used to enable the device to operate as intended, for examples leads, programmers, controllers, battery packs, software applications, implant kits and refill kits.
IVDD, In Vitro Diagnostic Directive, 98/79/EC

- perform tests on samples, such as blood, urine, tissue, taken away from the human body to help detect infection, diagnose a medical condition, prevent disease or monitor drug therapies.
- Reagent, Reagent Product, Calibrator, Control Material, Kit, Instrument, Apparatus, Equipment, System
- examination of specimen, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: concerning a physiological or pathological state of health or disease, or concerning a congenital abnormality, or to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures.

- HIV test kits
- Immunoassay analysers
- Blood gas analysers
- The calibrators and control materials used to verify the performance of the analysers
- Specimen receptacles and blood collection tubes
- Blood glucose meters and strips
Classification I: Non-invasive Devices

ORDER
1. Either do not breach patient or contact only intact skin
   - Class I
2. Channeling or storing for eventual administration
   - Class I
3. Modify biological or chemical composition of blood, body liquids, other liquids intended for injection
   - Class IIb
4. In contact with reinserted skin (mechanical barriers - absorb exudates)
   - Class I
   * or *
   - For use with blood, other body fluids, organs, tissues
     - Class IIa
   * or *
   - May be connected to an active medical device
     - Class IIa
   * or *
   - Only filtration, cannulation or exchange of gas or heat
     - Class IIb
   * or *
   - Intended for wounds which breach dermis and heal only by secondary intent
     - Class IIb
   * or *
   - Intended to manage microenvironment of wound + others
     - Class IIb
Classification II: Invasive Devices

Ila: Transient or short term

Ilb: Long-term use
Classification II-III: Active Devices

SPECIAL RULES

- **Rule 13**
  Devices incorporating integral medicinal product liable to act in any way on human body
  - III

- **Rule 14**
  Devices used for contraception or prevention of sexually transmitted diseases
  - III

- **Rule 15**
  Specific for disinfecting, cleaning, rinsing devices - for contact lenses
  - III

- **Rule 16**
  Non active devices to record X-ray diagnostic images
  - III

- **Rule 17**
  Devices utilizing animal tissues or derivatives (not devices in contact only with intact skin)
  - III

- **Rule 18**
  Blood Bags
  - III
4. Special Rules

4.1. Rule 13

- All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive M5 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.

- All devices incorporating, as an integral part, a human blood derivative are in Class III.

4.2. Rule 14

- All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III.

4.3. Rule 15

- All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIa. All devices intended specifically to be used for disinfecting medical devices are in Class IIa. Unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb.

- This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.

4.4. Rule 16

- Devices specifically intended for recording of X-ray diagnostic images are in Class IIa.

4.5. Rule 17

- All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.

5. Rule 18

- By derogation from other rules, blood bags are in Class IIb.
## Ethicon Examples

<table>
<thead>
<tr>
<th>Class</th>
<th>Pictures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>![Class I Image]</td>
</tr>
<tr>
<td>Class IIa</td>
<td>![Class IIa Image]</td>
</tr>
<tr>
<td>Class IIb</td>
<td>![Class IIb Image]</td>
</tr>
<tr>
<td>Class</td>
<td>Definition</td>
</tr>
<tr>
<td>-------</td>
<td>------------</td>
</tr>
<tr>
<td>Class III</td>
<td>central circulatory system</td>
</tr>
<tr>
<td>Class III</td>
<td>central nervous system</td>
</tr>
<tr>
<td>Class III</td>
<td>biological effect / mainly absorbable</td>
</tr>
<tr>
<td>Class III</td>
<td>Substance, if used separately, medicinal substance &amp; acts with ancillary action to device</td>
</tr>
<tr>
<td>Class III</td>
<td>human blood derivative / animal tissue or derivatives</td>
</tr>
</tbody>
</table>
Clinical, technical and biological characteristics shall be taken into consideration for the demonstration of equivalence

Clinical:

- used for the same clinical condition (including when applicable similar severity and stage of disease, same medical indication), and
- used for the same intended purpose, and
- used at the same site in the body, and
- used in a similar population (this may relate to age, gender, anatomy, physiology, possibly other aspects), and
- not foreseen to deliver significantly different performances (in the relevant critical performances such as the expected clinical effect, the specific intended purpose, the duration of use, etc.).

Technical:

- be of similar design, and
- used under the same conditions of use, and
- have similar specifications and properties (e.g. physicochemical properties such as type and intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, surface texture, porosity, particle size, nanotechnology, specific mass, atomic inclusions such as nitrocarburising, oxidability), and
- use similar deployment methods (if relevant), and
- have similar principles of operation and critical performance requirements.

Biological: Use the same materials or substances in contact with the same human tissues or body fluids.
Partial equivalency is not accepted.
Equivalency: Technological - Risk vs Benefit of surgery may need to be included as part of the device

How is device deployed? What are the associated risks?
Equivalency: Competitive Product Testing

versus

ETHICON

PRODUCT TESTING INSTITUTE

Medtronic

COVIDIEN
Case Study

Equivalency is challenged

MEOW

ROAARRR

Similar Risk?

Same intended purpose?

Similar material?

Similar Performance / Technology?

Indication: central circulatory system
Type: suture

Indication: central nervous system
Type: suture
During the manufacturing process, the Shiley was redesigned from a 60 degree opening heart valve to 70 degree
Case Study: Shiley Heart Valves, U.S. Food and Drug Administration approved for sale in 1979, were discontinued in 1986. CE denied the claim.
Quiz Time: What would this be in FDA and CE Mark Standards?

<table>
<thead>
<tr>
<th>Device</th>
<th>Abnormal Breath Sound Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>The device is intended to measure abnormal breath sound, such as wheeze, rhonchi, and whistling.</td>
</tr>
<tr>
<td>Physical State</td>
<td>An electronic device</td>
</tr>
<tr>
<td>Technical Method</td>
<td>It is a hand-held electronic measurement device that utilizes an acoustic sensor to acquire, amplify, filter, record and analyze pulmonary sounds from the trachea for the presence of breath sounds such as wheeze.</td>
</tr>
<tr>
<td>Target Area</td>
<td>Trachea</td>
</tr>
<tr>
<td>Regulation Medical Specialty</td>
<td>Anesthesiology</td>
</tr>
</tbody>
</table>
Quiz Time: What would this be in FDA and CE Mark Standards?

<table>
<thead>
<tr>
<th>Device</th>
<th>Material, Impression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>Impression material used in making dental molds of teeth.</td>
</tr>
<tr>
<td>Physical State</td>
<td>Material only</td>
</tr>
<tr>
<td>Target Area</td>
<td>Oral</td>
</tr>
<tr>
<td>Regulation Medical Specialty</td>
<td>Dental</td>
</tr>
<tr>
<td>Device</td>
<td>Material, Impression</td>
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