



INTERNATIONAL  
**TRADE**  
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# Medical Devices: CE Marking Step-by Step



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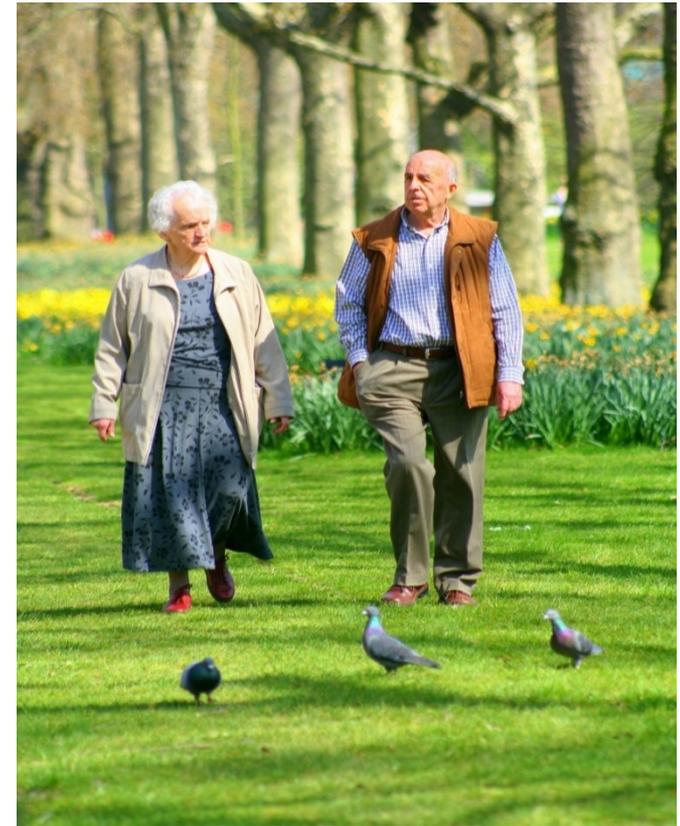
# Overview

- Introduction
- CE marking in 8 Steps
  - intended purpose
  - classification
  - essential requirements
  - conformity assessment
  - technical documentation
  - CE marking
  - Declaration of Conformity
  - authorized representative
- Other relevant legislation
- Information sources, websites



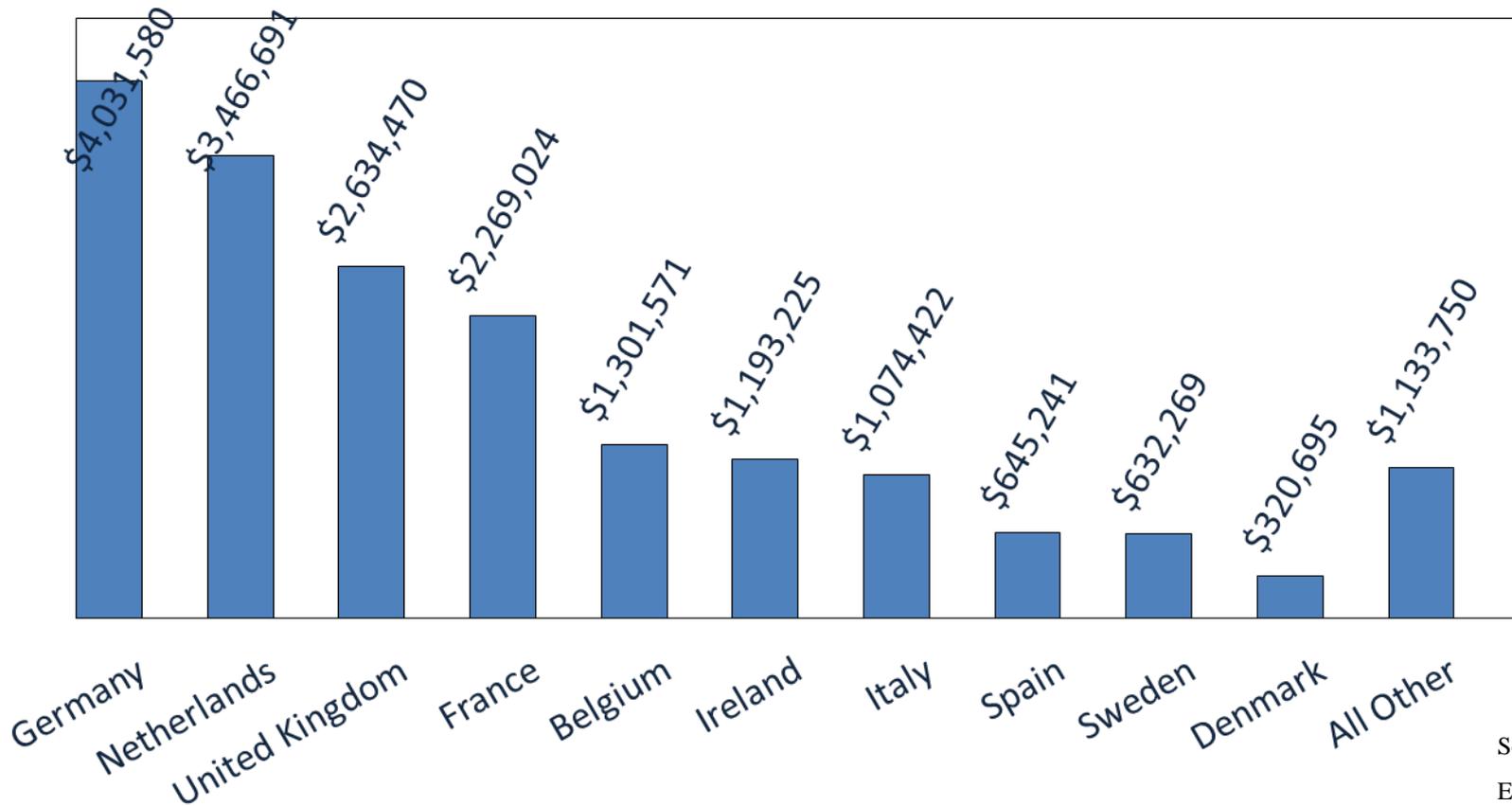
# Factors driving powerful European markets

- Vigorous economy
- High level of healthcare spending as a proportion of GDP
- An aging population. Evolution by 2050:
  - ❑ Fall in the working-age population: - 40 M
  - ❑ Fall in the number of young people aged 15 to 24 : -14 M
  - ❑ Life expectancy for women : 85.6 years
  - ❑ Life expectancy for men : 80.5 years
- High healthcare standards





# U.S. Medical Device Exports to EU 27



Seattle - May 2011  
(In thousands of Dollars, 2006)



# The EU framework: main characteristics

- No Food and Drug Administration: the European Commission (EC) handles the task of harmonizing requirements and regulating medical devices.
- Three Medical Devices Directives (MDDs): implantable, non-implantable and *in vitro* diagnostic medical devices.
- Regulatory framework generally considered open and transparent, largely based on international standards.



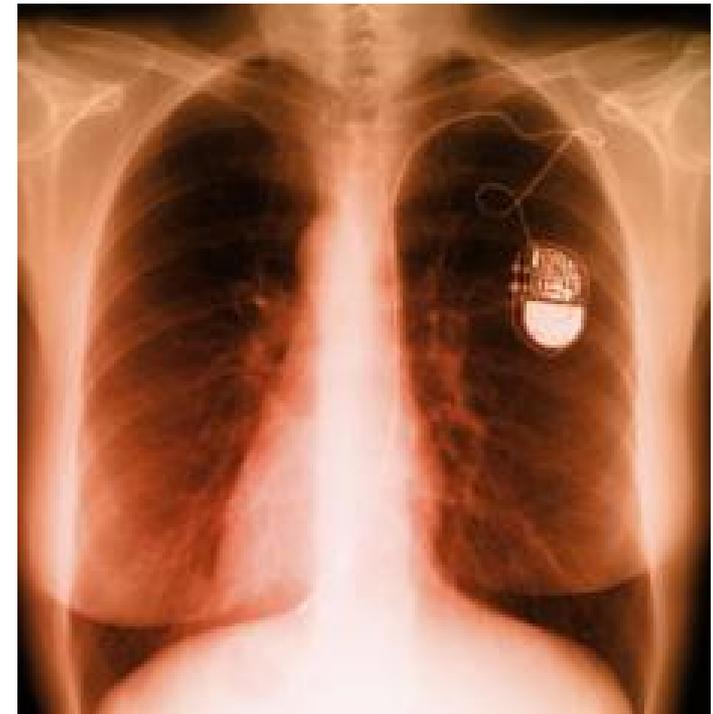
# Covered Medical Devices (1/3)

## Active Implantable Medical Devices (AIMD)

(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;”

*Example: heart pacemakers*

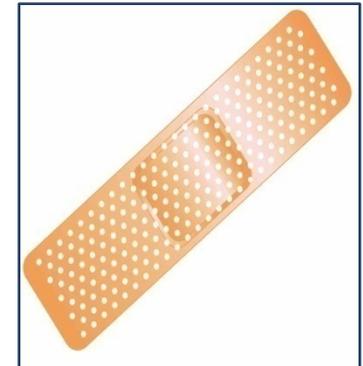


# Covered Medical Devices (2/3)

## Medical Devices (MD)

(Directive 93/42/EEC)

“Medical Device means any instrument, apparatus, appliance, software, material or other article (...) including the software (...) intended by the manufacturer to be used for human beings “ for several purposes such as diagnosis, monitoring, treatment and “which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means”;



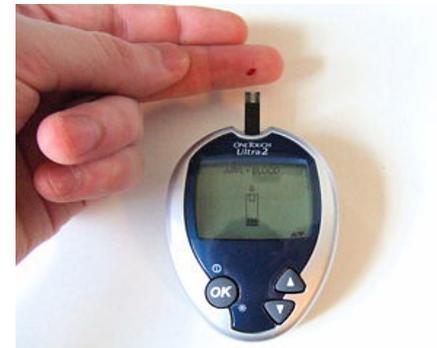


# Covered Medical Devices (3/3)

## In Vitro Diagnostic Medical Devices (IVD)

(Directive 98/79/EEC)

“Reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system (...) intended by the manufacturer to be used in vitro for the examination of specimens (...) derived from the human body (...) for the purpose of providing information” concerning a pathological state, a congenital abnormality, or to determine the compatibility with potential recipients, or to monitor therapeutic measures.





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# Bringing your medical device to the EU market: CE-marking step-by-step



# Step 1: what is the product? (1/2)

- Is the product a medical device according to the medical devices directives?
- What kind of medical device is the product (IVD, AIMD, MD)?

Depends on the intended purpose and whether the product fits the definition of the directives.



# Step 1: what is the product? (2/2)

## Borderline issues

It may sometimes be difficult to determine:

- If a product is a medical device (whether MD, IVD or AIMD)

*Examples: thermomixers intended to control the temperature of liquids in closed micro test tubes, gold implants for treatment of osteoarthritis...*

- If a medical device is an MD, or an IVD, or an AIMD:

*Example: bone-anchored hearing aids...*

## Resources for manufacturers with borderline issues:

- EC Manual on borderline and classification of medical devices

[http://ec.europa.eu/consumers/sectors/medical-devices/files/wg\\_minutes\\_member\\_lists/version1\\_9\\_borderline\\_manual\\_en.pdf](http://ec.europa.eu/consumers/sectors/medical-devices/files/wg_minutes_member_lists/version1_9_borderline_manual_en.pdf)

- Official interpretation from a Competent Authority



# Step 2: classification (1/5)

## Overview

- Medical devices (MD, IVD and AIMD) fall into various risk categories.
- US and EU classification systems don't match perfectly.

**Compliance procedures depend on classification →  
Important to classify properly!**



## Step 2: classification (2/5)

### Classification of MD

- A 'risk based' system based on the vulnerability of the human body
- Four risk classes: I (low risk), IIa, IIb and III (high risk)

Annex IX of Directive 93/42/EEC contains the classification rules.



# Step 2: classification (3/5)

## Examples

Class	Examples
Class III	Cardiovascular catheters, biological adhesives, aneurysm clips, spinal stents, prosthetic heart valves...
Class IIb	Hemodialysers, gradient medium for sperm separation, haemodialysis concentrates
Class IIa	Syringes for infusion pumps, fridges specifically intended for storing blood, antistatic tubing for anesthesia, anesthesia breathing circuits, pressure indicator, pressure limiting devices...
Class I	Devices used to immobilize body parts (e.g. cervical collars), devices intended in general for external patient support (e.g. hospital beds, walking aids, wheelchairs, stretchers...), corrective glasses, stethoscopes for diagnosis, incision drapes, conductive gels...



# Step 2: classification (4/5)

## Classification of IVD

- Classification into 4 groups: general IVD tests, self-tests, tests listed in Annex II A and tests listed in Annex II B.
- Annex IIA and IIB: higher risks
  - *IVDs in Annex IIA: intended for the detection in human specimens of markers of HIV infection, HTLV...*
  - *IVDs in Annex IIB: intended for the detection in human specimens of markers of cytomegalovirus, chlamydia, PSA...*



# Step 2: classification (5/5)

## Classification of AIMD

High risk, invasive: one single risk class

### Resources for manufacturers with classification issues

- EC guidance document on classification of medical devices

[http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2\\_4\\_1\\_rev\\_9\\_classification\\_en.pdf](http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_4_1_rev_9_classification_en.pdf)

- Official interpretation from a Competent Authority



# Step 3: meet essential requirements (1/4)

## Essential requirements (ER) for the protection of health and safety:

- Form the core of the 3 directives.
- Are set out in general terms.
- Cover risks and hazards that may occur at the design, production and handling stages.
- Are listed in Annex I of each directive.

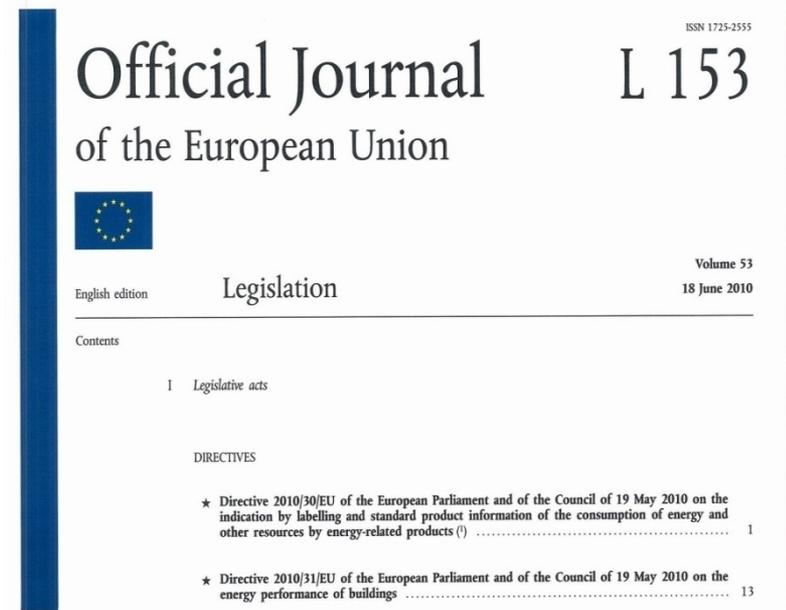
*Example of ER: "Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition."*



# Step 3: meet essential requirements (2/4)

## EU-wide Harmonized standards

Compliance with harmonized standards provides a presumption of conformity with the corresponding requirements of the directive.





# Step 3: meet essential requirements (3/4)

## A few examples EU-wide Harmonized standards

- EN ISO 14971:2009 (Risk management)
- EN 980:2008 (Symbols for use in the labeling of MD)

*List of EU Harmonized Standards for MD/IVD/AIMD:*

[http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm)

*Standards can be bought in the US through the American National Standards Institute*





# Step 4: follow a CAP (1/4)

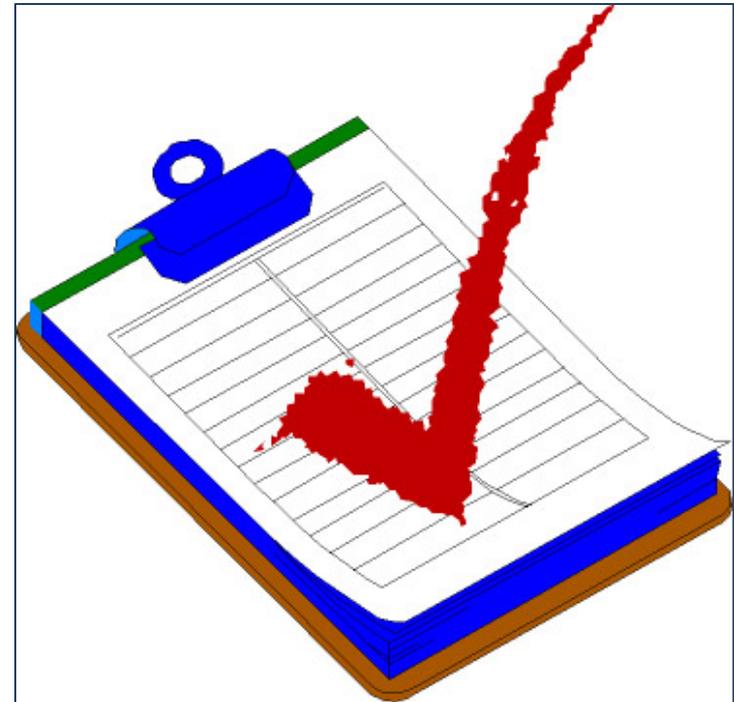
## Conformity Assessment procedures (CAP)

- CAPs allow manufacturers to demonstrate the conformity of their device with the provisions of the directive.
- The choice of the CAP is determined by the classification of the device and the preference of the manufacturer for a given CAP.
- CAPs address the design and production stages:

## Step 4: follow a CAP (2/4)

### Range of CAP

- Low-risk products (e.g. class I MD) generally allow **self-certification**.
- CAPs applicable to higher-risk products will require the services of a **third party** (“EU Notified Body”) depending on the classification of the device.





# Step 4: follow a CAP (3/4)

## Role of Notified Bodies (NB)

- For all AIMD, certain IVD and MD (Class IIa and above).
- NB are accredited test laboratories based in the EU.
- Only an accredited EU NB can make the final assessment of conformity with the directives and deliver a certificate.
- A US based subcontractor of an EU NB can handle the tests for certification, but the certificate of conformity will still have to be supplied by the EU-based NB.

*List of accredited NB:*

<http://ec.europa.eu/enterprise/newapproach/nando/>



## Step 4: follow a CAP (4/4)

### Quality Management System

- Required for all devices (except Class I non sterile/non measuring).
- Most companies apply EN ISO 13485 to comply with QMS requirements (not mandatory).
- Implementation of a QMS may take 3-4 months to a year.



# Step 5: Assemble the Technical Documentation

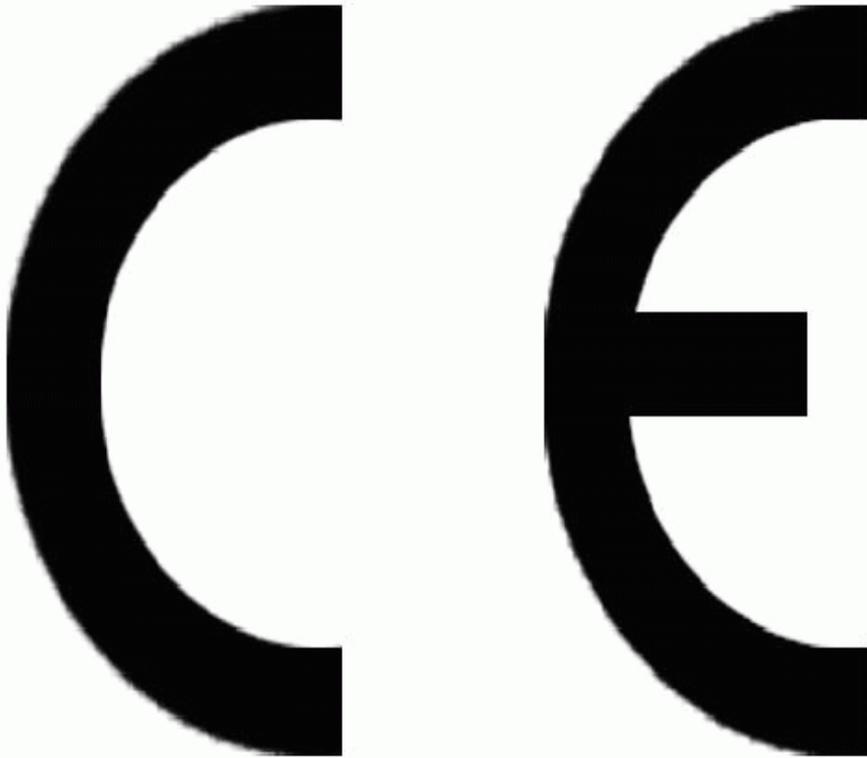
## The Technical Documentation:

- Contains all relevant information to support the claims of compliance with the requirements of the directive.
- Must be kept at the disposal of national surveillance authorities.





## Step 6: affix CE-marking



The CE-marking symbol:

- Is affixed to the device and accompanying documents.
- Demonstrates that the manufacturer has complied with the applicable directive (s) and is not a quality sign

*When a NB intervenes, its ID number must appear below the CE-marking.*



# Step 7: draw up a Declaration of Conformity

- For all devices
- One-page document on which the manufacturer of a medical device "declares" his product's "conformity" with the Essential Requirements of the Directive.
- To be kept at the disposal of authorities.



## Step 8: appoint an Authorized Representative

- US-based manufacturers must appoint an EU-based authorized representative (rep) unless they have a registered business in the EU.
- Primary task of the rep: be the point of contact for national Competent Authorities (CA)
- The rep also notifies CA when a new class I MD is brought to the market and registers devices in individual Member States.

Identify a rep: <http://www.earmed.org/>



## Other applicable EU legislation

In addition to the MDD, other directives may apply:

“Technology” directives:

- 2006/95/EC Low Voltage
- 2004/108/EC Electromagnetic Compatibility
- 2006/42/EC Machine Safety

“Environment” directives:

- 2002/96/EC Waste Electrical and Electronic Equipment
- 2002/95/EC Restriction of Hazardous Substances (future)



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# Information Sources

- Contact the Commercial Service in Brussels:  
[www.buyusa.gov/europeanunion](http://www.buyusa.gov/europeanunion)
  - Medical Devices Specialist Lucie Mattera  
([lucie.mattera@trade.gov](mailto:lucie.mattera@trade.gov))
  - Standards Specialist Sylvia Mohr  
([sylvia.mohr@trade.gov](mailto:sylvia.mohr@trade.gov))



- Contact the U.S. Commercial Service - [www.buyusa.gov](http://www.buyusa.gov)
- See Also:
  - [http://ec.europa.eu/consumers/sectors/medical-devices/index\\_en.htm](http://ec.europa.eu/consumers/sectors/medical-devices/index_en.htm)
  - <http://ec.europa.eu/enterprise/policies/europe-an-standards/documents/harmonised-standards-legislation/list-recent-publications/>
  - <http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.main>



# Underwriters Laboratory

## Websites

Health Sciences: [www.ul.com/medical](http://www.ul.com/medical)

Links to:

- Medical Devices
- Services provided by UL