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Ooh La Labeling: *Device Labeling In the EU*

Several EC Directives and many standards drive the development of medical device labeling in the EU. Compliance with labeling requirements is a formidable task for medical device companies. The penalties for non-compliance can be severe and range from delays in product commercialization to confiscation of goods and the levying of monetary fines.

Herein we examine the medical device labeling requirements that medical products companies must comply with to achieve commercialization in the European Union.



Welcome.

Today's Discussion:

Labeling Overview

Device Labeling: EU



Mr. Morroney combines certifications in regulatory affairs, compliance auditing, and quality systems with more than 15 years of industry experience in regulatory affairs, clinical

operations, quality, and IT to effectively deliver new medical product approval and compliance solutions.

Mr. Morroney has led a broad range of projects for large multinationals and development-stage medical products companies. His casework typically includes U.S. and international regulatory strategy and product registrations, product engineering, quality systems development and implementation, GMP compliance, and clinical development. He has successfully obtained U.S. and international marketing approvals for numerous medical products.

His experience includes senior supervisory positions in manufacturing, production, and process development at Boeing, where he received numerous industry awards for quality engineering, production, and process improvement and design. He holds a Regulatory Affairs Certification in Medical Products from The Regulatory Affairs Professional Society, and a Quality Auditing Certification from The American Society for Quality. He holds numerous additional quality certifications and memberships to the American Society of Quality, The Society of Manufacturing Engineers, and The Quality, Engineering and Manufacturing Association.

“A thorough knowledge of a country’s labeling regulations is required to ensure that medical products are properly labeled, and risks are reduced thereby enabling unimpeded access to commercial markets.”

Richard Morroney, R.A.C., C.Q.A.
Vice President

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Overview



“Many hazards associated with medical devices do not arise from their design or manufacture, but rather from the manner in which the devices are used. Devices are often not properly labeled as to specific operating instructions.”¹

1. U.S. House. 1976. Committee on Interstate and Foreign Commerce. *Medical Device Amendment of 1976*. 84th Congress, 2nd Session, H. Rept. 883.



Why do we need labeling?

The Purpose of Labeling is to:

“Communicate safety and performance related information to users of medical devices and/or patients as well as to identify individual devices.”¹



What do we mean when we say “labeling”?

Labeling Includes:

- ***User Manuals;***
- ***Service Manuals;***
- ***Quick Reference Guides;***
- ***Package Inserts;***
- ***Device Placards;***
- ***Package Labels;***
- ***Shipping Labels;***
- ***Software-driven User-Interface Data;***
- ***Marketing Advertisements;***
- ***Website Pages;***
- ***Sales Literature; and***
- ***TV, Newspaper, and Radio Advertisements.***

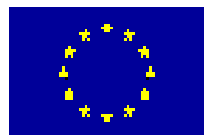


What do we mean when we say “label”?

The Term Label Refers to:



A display of written, printed, or graphic matter upon the immediate container of any article...



Written, graphic, or printed matter on a device or any of its containers or wrappers.



Any legend, word, or mark attached to, included in, belonging to, or accompanying any device or package.



A display of printed information.



Labeling errors, i.e., misbranding, can lead to serious problems.

Problems Include:

- *Delays in Product Commercialization;*
- *Quarantine of Imports;*
- *Mandatory Field Actions;*
- *Product Recalls; and*
- *Civil and Criminal Penalties.*

Labeling errors include: falsely labeling products, omitting required information, and failure to control labeling operations.



Labeling must convey the information that end-users need to safely use the device as intended by the manufacturer.

User Manual Information Includes:

- ***Risks;***
- ***Warnings;***
- ***Cautions;***
- ***Adverse Reactions;***
- ***Indications for Use;***
- ***Contraindications;***
- ***User Assistance;***
- ***Table of Contents;***
- ***Device Description;***
- ***Environmental Effects;***
- ***Set-up Instructions;***
- ***Device Test Procedures;***
- ***Troubleshooting;***
- ***Operating Instructions;***
- ***Cleaning;***
- ***Maintenance;***



Labeling must convey the information that end-users need to safely use the device as intended by the manufacturer.

User Manual Information Includes:

- ***Storage;***
- ***Accessories and Supplies;***
- ***Technical Information;***
- ***Summary;***
- ***Index; and***
- ***Date: Issued/Revised.***



Labeling developers must take action to reduce labeling problems...

Development Considerations:

- 1. Consider the Audience;***
- 2. Organize the Information;***
- 3. Write to the Reader;***
- 4. Choose Words Carefully;***
- 5. Avoid Lengthy and Elegant Prose;***
- 6. Carefully Plan Instructions;***
- 7. Use Appropriately Structured Warnings and Cautions; and***
- 8. Evaluate the Labeling.***



... and develop good designs.

Design Considerations Include:

- 1. *Conditions for Use;***
- 2. *Layout;***
- 3. *Physical Attributes;***
- 4. *Font Type and Size;***
- 5. *Highlighting;***
- 6. *White Space;***
- 7. *Use of Illustrations and Graphics; and***
- 8. *Use of Color.***



Most countries have specific requirements for labeling of medical devices.

- ***The labeling requirements vary from specific details to broad, general requirements;***
- ***The labeling requirements are usually “minimum” requirements; and***
- ***Manufacturers must augment the minimum requirements as appropriate:***
 - ***Include device-specific requirements specified in standards and guidance documents; and***
 - ***Include other information to enable the end-users to safely use the device.***





Various directives may be applicable when marketing medical devices in the European Union (EU).

Directives Include:

- ***The Medical Device Directive 93/42/EEC***
- ***The Active Implantable Medical Device Directive 90/385/EEC***
- ***The In Vitro Diagnostic Devices Directive 98/79/EC***
- ***The Radio and Telecommunications Terminal Equipment Directive 99/5/EC***

Directives make direct reference to other directives.



Other directives may impact the labeling of medical devices.

Directives Include:

- ***Proprietary Medicinal Products Directive 65/65/EEC***
- ***Low Voltage Equipment Directive 73/23/EEC***
- ***Packaging and Labeling of Dangerous Substances Directive 91/325/EEC***
- ***Packaging and Packaging Waste Directive 94/62/EEC***



Harmonized standards also play an important role in the framework of the directives.

Key Harmonized Standards Include:

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html>

Conformity with harmonized standards implies a presumption of conformity to essential requirements.



There is no requirement regarding the use of single or multiple-language labeling.

Official Languages of the EU:

Member State	Official Language(s)
<i>Austria</i>	<i>German</i>
<i>Belgium</i>	<i>Dutch, French, German</i>
<i>Cyprus</i>	<i>Greek, Turkish</i>
<i>Czech Republic</i>	<i>Czech</i>
<i>Denmark</i>	<i>Danish</i>
<i>Estonia</i>	<i>Estonian</i>
<i>Finland</i>	<i>Finnish</i>
<i>France</i>	<i>French</i>
<i>Germany</i>	<i>German</i>

The manufacturer is free to choose the type of labeling system best suited for a particular product.



There is no requirement regarding the use of single or multiple-language labeling.

Official Languages of the EU:

Member State	Official Language(s)
<i>Greece</i>	<i>Greek</i>
<i>Hungary</i>	<i>Hungarian</i>
<i>Ireland</i>	<i>English</i>
<i>Italy</i>	<i>Italian</i>
<i>Latvia</i>	<i>Latvian</i>
<i>Lithuania</i>	<i>Lithuanian</i>
<i>Luxembourg</i>	<i>French, German</i>
<i>Malta</i>	<i>Maltese, English</i>
<i>Netherlands</i>	<i>Dutch</i>

The manufacturer is free to choose the type of labeling system best suited for a particular product.



There is no requirement regarding the use of single or multiple-language labeling.

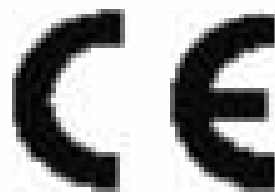
Official Languages of the EU:

Member State	Official Language(s)
<i>Poland</i>	<i>Polish</i>
<i>Portugal</i>	<i>Portuguese</i>
<i>Slovakia</i>	<i>Slovak</i>
<i>Slovenia</i>	<i>Slovenian</i>
<i>Spain</i>	<i>Spanish</i>
<i>Sweden</i>	<i>Swedish</i>
<i>United Kingdom</i>	<i>English</i>

The manufacturer is free to choose the type of labeling system best suited for a particular product.



CE marking signifies that a product conforms to all directives that are relevant to a given product.



Other markings may affix to a product and its packaging provided they don't interfere with the legibility and visibility of the CE mark.

I. Symbols are for reference only.



Medical devices covered by the directives must bear the CE mark.

CE Mark Locations Include:

- *The IFU;*
- *The device or its sterile package;*
- *The retail sales packaging.*

The mark must be accompanied by the ID # of the notified body when conformity assessment procedures are required.



Products may not qualify for CE marking under all applicable directives at all times.

Example: *CE marking is not permitted for investigational devices but may be required by other directives.*

Solution: *Manufacturers must clearly identify in the labeling, the directives with which the product complies.*



Under certain circumstances, devices are prohibited from bearing the CE mark.

Do Not Use the CE Mark When:

- *A device is intended for use in clinical investigations;*
- *An IVD device is undergoing performance testing;*
- *A device is custom-made.*



The **CE** mark is recognized by other European countries outside of the EU.

Countries That Require CE Mark:

<i>Austria</i>	<i>Poland</i>	<i>Malta</i>
<i>Belgium</i>	<i>Hungary</i>	<i>Norway¹</i>
<i>Cyprus</i>	<i>Netherlands</i>	<i>Portugal</i>
<i>Czech Republic</i>	<i>Iceland¹</i>	<i>Slovakia</i>
<i>Denmark</i>	<i>Ireland</i>	<i>Slovenia</i>
<i>Estonia</i>	<i>Italy</i>	<i>Spain</i>
<i>Finland</i>	<i>Latvia</i>	<i>Sweden</i>
<i>France</i>	<i>Liechtenstein¹</i>	<i>Switzerland¹</i>
<i>Germany</i>	<i>Lithuania</i>	<i>Turkey</i>
<i>Greece</i>	<i>Luxembourg</i>	<i>U.K.</i>

1. Countries of the European Economic Area (EEA).



Annex I of the MDD specifies the information that must be on the label and the Instructions For Use (IFU).

Requirements Include:

- ***General Labeling Provisions;***
- ***Devices with a Measuring Functions;***
- ***Particulars to be Present on the Label;***
- ***IFU; and***
- ***Patient Information.***



The MDD requires that each device be accompanied by the information needed to use it safely and to identify the manufacturer.

- ***The information should be placed on the device and/or packaging;***
- ***The information should be included in the documentation supplied with one or more devices in cases where individual packaging is not practical;***
- ***The function of user-adjustable controls and displays must be specified on the device and/or IFU; and***
- ***You must state the intended purpose on the label and in the IFU unless it is obvious to the user.***



Symbols should be used to convey the required information.

- ***Symbols must be legible when viewed under an illumination of 215 lux using normal vision;***
- ***Use the symbols specified in EN 980;***
- ***You can also use the symbols identified in ISO 15223 or IEC 60878; and***
- ***You may develop special symbols:***
 - ***Describe the special symbols in the device labeling documentation.***



DISETRONIC
extension set

Set für subkutane Infusion
Set for subcutaneous infusion
Set d'infusion sous-cutanée
Set per infusione sottocutanea
Set voor subcutane infusie
Set para infusión subcutánea

PE 80
MADE IN DENMARK
NON PYROGENIC

EN 980
80cm

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Do not reuse.

2003-10
515285
300.0138

LOT
REF

STERILE EO

Sterilität: nur bei unbeschädigter Verpackung
Sterility is guaranteed if package is undamaged
La stérilité est garantie si l'emballage est intact
Sterilità garantita a confezione integra
Steriliteit alleen bij onbeschadigde verpakking
Utilizar sólo con envase íntegro

Diatronik Medical Systems AG
3401 Burgdorf, Switzerland
Manufactured by MAERSK MEDICAL DR-4000

Note the use of EN 980 Symbols

Note the use of multiple languages.



Note the use of EN 980 symbols

Attention, See IFU ————

Method of Sterilization ————

Do Not Reuse ————

The image shows a rectangular medical device label. On the left side, there is a vertical green arrow pointing upwards with the text 'PEEL TO OPEN' written vertically. In the upper right quadrant, three symbols are circled in red: a warning triangle, a rectangular box containing the word 'STERILE', and a circle containing the number '2'. To the right of these symbols are three lines of text: 'Read instructions prior to use', 'CONTENTS STERILE unless seal is broken or packaging opened or damaged. Do not re-sterilize.', and 'This product is for single patient use only.'. Below these symbols and text is a large empty rectangular box. At the bottom of the label, the text reads 'Boston Medical Products, Inc. Westborough, MA 01581 USA' and 'LAD04' in the bottom right corner.



The MDD specifies requirements for devices that perform measuring functions.

- ***The stability and accuracy of the measuring function must meet the intended use of the device;***
- ***You must state the limits of accuracy in the labeling;***
- ***The measurement, monitoring, or display scales must meet accepted ergonomic principles; and***
- ***Displayed measurement results must be displayed in metric system units:***
 - ***Other units of measurement outside the SI system may be used.***



ER 13.3 of the MDD specifies the minimum label requirements for devices.

Requirements Include:

- ***Manufacturer's Identity;***
- ***Identity of the Device;***
- ***Sterile Device Marking;***
- ***Product Identification;***
- ***Expiration Dating;***
- ***Year of Manufacture;***
- ***Single-Use Devices;***
- ***Storage and Handling Conditions;***
- ***Special Operating Instructions;***
- ***Warnings and Precautions;***
- ***Marking for Special-Purpose Devices; and***
- ***Devices Incorporating Human Blood Derivatives.***



The label must bear the following manufacturer information:

- ***The name/trade name and address;***
- ***For imported devices:***
 - Manufacturer's name/trade name and address; and
 - Authorized representatives name and address; or
 - Importer name and address.



The label of sterile devices must bear the word “STERILE” and the method of sterilization.

Use the EN 980 Symbols:

STERILE

STERILE EO

STERILE R

STERILE 

STERILE A

A sterility assurance level of 10^{-6} must be achieved to be considered sterile in the EU.

I. Symbols are for reference only.



Devices and detachable components must be identified by batch, whenever reasonable and practical.

- ***Batch codes must be preceded by the word “LOT”.***
- ***Use the symbol:***

LOT

Device packaging and/or label must distinguish between identical or similar products sold in both sterile and non-sterile condition.

I. Symbols are for reference only.



The expiration date is expressed as a four-digit year and a two-digit month.

- ***The expiration date may be identified by using the “USE BY” symbol.***



When more precision in specifying a date is required add a two-digit day (i.e., yyyy-mm-dd).

I. Symbols are for reference only.



If an expiration date is not included, the label must bear the four-digit year of manufacture.

- ***The year of manufacture may be included in the lot or serial number.***
- ***The year of manufacture may be identified by the appropriate text or by using the “Date of Manufacture” symbol, when provided as a separate item of information.***



I. Symbols are for reference only.



The label of devices that are intended to be used once must bear an indication that the device is for single use.

- ***The “Do Not Reuse” symbol may be used to indicate a single use device.***



- ***Phrases can also be used:***
 - Do not reuse;
 - Single use only;
 - Use only once.

I. Symbols are for reference only.



Special storage and handling conditions must be provided on the outer label of the device.

- ***Devices and their packaging must meet their design specifications for storage, handling, and transport.***
- ***In general, devices should be protected from extreme environmental conditions.***

Include this information when a device must be maintained within specific environmental parameters.



The label must bear any warnings and cautions that must be taken.

Warning:

Important information can/may be overlooked by the end-user when warning and caution lists become voluminous.

The labeling developer should focus on the warnings and conditions associated with novel or unfamiliar device features that are not intuitively obvious.



The labeling of custom-made and investigational devices (including IVD performance evaluations) must bear specific phrases.

Custom-Made Devices:

Custom-made device

Investigational Devices:

Exclusively for Clinical Investigators

IVD Performance Evaluations:

For Performance Evaluations Only



The MDD requires that the IFU must be on the device itself and/or included on the packaging for each unit.

IFU Requirements Include:

- ***Label Details;***
- ***Intended Performance;***
- ***Connection to Other Medical Devices;***
- ***Installation and Maintenance;***
- ***Reciprocal Interference;***
- ***Sterile Packaging;***
- ***Reusable Devices;***
- ***Device Preparation;***
- ***Radiation-Emitting Devices; and***
- ***Implantable Devices.***

The IFU must be included in the packaging for every device, except for Class I or IIa device.



The IFU must contain the details from the label.

- ***Include all applicable information except:***
 - The lot number; and
 - The expiration date; or
 - The year of manufacture.



The IFU must include all performance claims.

- ***Performance claims must be verifiable.***
- ***The user must be warned of any undesirable side-effects.***
- ***Include clinical data where appropriate.***



The IFU must include details if a device must be installed with or connected to other medical devices.

Details Include:

Providing the characteristics of the device so that the user can identify the current devices to use in order to obtain a safe combination.

The extent of the information provided should take into account the experience of the end-users.



The IFU must contain the information needed to verify whether the device is properly installed and can be safely and properly operated.

- ***Details regarding the nature and frequency of maintenance and calibration is required to ensure that devices operate safely and properly at all times.***

Step-by-step procedures may be included in a separate manual.



The IFU must contain information regarding the risks of reciprocal interference posed by the presence of other devices.

- ***Include details regarding risks associated with the interaction between devices or with other medical treatments that may result in:***
 - Death or injury to humans;
 - Damage to the device or other devices; and
 - The rendering of treatments to be ineffective.



The IFU must include instructions in the event of damage to any sterile packaging.

Instructions Include:

- ***Details for returning the device to the manufacturer; or***
- ***Details for resterilization including appropriate methods.***
 - Warnings and cautions regarding inappropriate sterilization.



The IFU must include appropriate details for the processing for the re-use of reusable devices.

Processing Devices Include:

- ***Cleaning;***
- ***Disinfecting;***
- ***Sterilization;***
- ***Packaging;***
- ***Method of sterilization; and***
- ***Restrictions on the number of re-uses.***



The IFU must contain sufficient details to prepare devices for use.

Details Include:

- ***Cleaning and sterilization instructions;***
- ***Final assembly instructions; and***
- ***Handling instructions.***

Do not include handling instructions that are implicit to normal use, e.g., handling sterile devices under aseptic conditions.



The IFU must contain details regarding the risks of radiation-emitting and implantable devices.

- ***For radiation-emitting devices, include the:***
 - Nature;
 - Type;
 - Intensity; and
 - Distribution of the radiation.

- ***For implantable devices include information regarding the avoidance of certain risks associated with the implantation of the device including:***
 - Operating instructions;
 - Warnings and cautions;
 - Risk of rejection;
 - Erosion through the skin;
 - Embolisms; and
 - Infections.



The IFU should also contain information for medical professionals for use in patient consultations.

Topics Include:

- ***Changes in Performance;***
- ***Exposure to Environmental Conditions;***
- ***Administration of Medicinal Products;***
- ***Disposal of the Device;***
- ***Medicinal Substances Incorporated into the Device; and***
- ***Measuring Accuracy.***



You must incorporate other sources of information in addition to the MDD requirements to ensure that the labeling is compliant.

The Labeling Must Satisfy:

- ***All requirements in Annex I of the MDD;***
- ***Requirements specific to any standards used to demonstrate compliance; and***
- ***Requirements deemed necessary by the manufacturer for the safe use of the device.***



The EN 60601-1 standard specifies additional labeling requirements for active medical devices.

Requirements Include:

- ***General requirements for markings on electrical medical equipment;***
- ***Specifications for marking both the inside and outside of the equipment;***
- ***Specifications for marking controls and instruments;***
- ***Requirements for document accompanying medical electrical equipment.***



Markings on the outside of equipment are dependent on the type of power source.

Power Sources Include:

- *Mains-powered equipment;*
- *Internally powered equipment; and*
- *Equipment supplied from a specific source.*



Medical electrical equipment must have a permanent label on its external surface that identifies equipment type.

Use the Following Symbols:



Type B



Type BF



Type CF

Equipment types vary based on risk of current flow through a person upon contact with the device.

I. Symbols are for reference only.



When equipment has more than one part in contact with the body and the parts offer different degrees of protection, appropriate symbols must be marked on each applied part.

Use Applied Part Symbols:



Defib. Type B



Defib. Type BF



Defib. Type CF

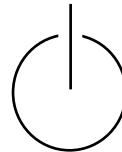
Special markings are required on parts that have been protected against the effects of cardiac defibrillator discharge.

I. Symbols are for reference only.



The standard requires that all operator controls and indicators be clearly identified.

- ***The main power switch must be identified.***
 - Use on/off symbols; or



- Indicator light; or
- Other.

The use of indicator lights and buttons must follow standard usage requirements regarding their colors/meanings.

I. Symbols are for reference only.



The positions of switches and controls must be clearly identified.

- ***When a control adjusts a device characteristic that could result in a safety hazard, the control must be equipped with:***
 - An associated indicating device; or
 - An indication of the direction in which the magnitude of the characteristic changes.

- ***Numeric indicators must be expressed in SI units.***



Permanently installed equipment must have the voltage (nominal supply or range) marked either on the inside or outside of the equipment.

- ***The terminal for connection to the neutral-supply conductor must be indicated by the capital letter “N”.***

- ***The protective earth symbol must be marked:***

– Use this symbol:



- ***Equipment that connects to a terminal box that reaches more than 75°C must include the statement near the points of connection:***
 - For supply connection, use wiring materials suitable for at least ___ °C.

Markings should be located adjacent to supply-connection terminals.

I. Symbols are for reference only.



The source of information required may introduce conflicting labeling requirements in content or presentation.

Resolve Labeling Conflicts as Follows:

- 1. The requirements of the directive have precedence over other requirements;***
- 2. The requirements of harmonized standards override requirements in non-harmonized standards; and***
- 3. Specific standards override general standards.***



Questions and Answers

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