

# MEDICAL DEVICE LABEL: BEFORE AND AFTER EU MDR/IVDR



EU MDR introduces additional information that needs to be included on labels, forcing organizations to design new label templates that make room for data not previously part of the labeling system. It's both a design and a data challenge, and they must quickly be addressed to avoid a sticky situation.

- 01

**UDI applied in Europe**  
 UDI has its own dedicated section within EU MDR.
- 02

**More serial and lot numbers**  
 This change falls under the UDI remit. However, EU MDR requires more products to be serialized than FDA UDI.
- 03

**Highlight authorized EU representatives**  
 Every manufacturer whose registered place of business is outside the EU is required to have a licensed EU representative.
- 04

**Warnings & precautions must be on label**  
 This change will probably have the biggest impact. MDR mandates that all warnings relating to a device must be printed on the label.
- 05

**Label must indicate blood and tissue derivatives**  
 EU MDR provides regulation for medtech innovations not previously covered by MDD; i.e nanotechnology, the use of computer software or medicines.
- 06

**Label must indicate CMR or endocrine-disrupting substance**  
 Devices with a presence of carcinogenic, mutagenic or toxic to reproduction (CMR) substances must declare so on the label. These requirements go much further than MDD.
- 07

**Include reprocessing cycles**  
 This is another huge data challenge. Under EU MDR, labels for single-use devices that can be reprocessed must detail the maximum amount a device can be reprocessed as well as the number of times the individual device has been reprocessed to date.
- 08

**eIFUs (electronic Information for Use)**  
 EU MDR also introduces requirements around electronic IFUs and the 'absorption of substances' that dictate changes in labeling processes.
- 09

**Label spacing differences**  
 In order to address the fact that new mandatory content – such as the addition of warning & precautions (see #4) – is almost certainly going to create congestion, the recent Final Ruling by the FDA no longer requires English text to appear alongside symbols in order to free up label space.
- 10

**Medical Device symbol**  
 Under EU MDR, manufacturers of medical devices must now include a new field on their labels; a clear symbolic indication that the device is a medical device.

THE OLD

THE NEW

Sample Product

Product Name

Product Description

Size: 150mm

REF

PROD12345

LOT

LOT123

Expiry Date

2018-01-01

Date of manufacture

2013-01-01

Rx Only

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

Quantity

1

CE

0123

STERILEEO

Sterilized by ethylene oxide treatment

Temperature Limitation

-5°C 130°C

Humidity Limitation

10 70

Do Not Use if Package is Damaged

Single Use

Do Not Re-sterilize

Caution

MR Conditional

Consult Instructions for Use

Manufacturer

Company Name

Address

Label spacing difference

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Sample Product

Product Name

Product Description

Size: 150mm

REF

PROD12345

LOT

LOT123

SN

123456

Expiry Date

2018-01-01

Date of manufacture

2013-01-01

10

7

MD

Rx Only

1/5

STERILEEO

Sterilized by ethylene oxide treatment

Temperature Limitation

-5°C 130°C

Humidity Limitation

10 70

Do Not Use if Package is Damaged

Single Use

Do Not Re-sterilize

Caution

MR Conditional

Consult Instructions for Use

Manufacturer

Company Name

Address

5&6

1&2

Warning: Die Verwendung dieses Geräts kann zu Verletzungen Ihres ungeborenen Kindes verursachen. Verwenden Sie nicht, wenn Sie schwanger sind.

Warning: Using this device can cause injury to your unborn baby. Do not use if you are pregnant.

Advertencia: El uso de este dispositivo puede causar lesiones a su bebé por nacer. No lo use si está embarazada.

Attention: L'utilisation de cet appareil peut causer des blessures à votre bébé à naître. Ne pas utiliser si vous êtes enceinte.

Avvertimento: L'uso di questo dispositivo può causare lesioni al nascituro. Non usare se sei incinta.

8

for Symbols Glossary

http://eu.manufacturesite.com

CE

0123

EC

REP

Company Name

Address

3

## CHANGES TO THE NEW EU MDR LABEL

1&2

**UDI content:**  
 More serial and lot numbers

3

**Highlight authorized EU representatives**

4

**Warnings & precautions must be on label**

5&6

**Label must indicate CMR/Endocrine-Disrupting Substances/Blood and Tissue**

7

**Include reprocessing cycles**

8

**Add eIFU link**

9

**Label spacing differences**

10

**Include Medical Device symbol**

## GLUING IT ALL TOGETHER

Achieving compliance with EU MDR will naturally create labeling challenges for medical device companies. Companies therefore need to ensure their current labeling system is fit for purpose. But they need to do it soon. Although EU MDR will not be fully enforced until 2022, the birth of EUDAMED in 2020 means companies could be prevented from registering or re-registering products if they don't address associated labeling challenges ahead of its introduction. Failure to do so could mean companies can't market their products in Europe.

## SELECT A LABELING SOLUTION THAT CAN ADAPT TO A CHANGING WORLD

Your labeling system needs to be compliant with EU MDR by 2020. However, do not lose sight that Microsoft and Oracle are ending support for several operating systems and databases by 2020. Ensure you only touch your labels once, while addressing both impending deadlines.

Saves Time

Reduces Waste

Eliminates Human Error

Meets FDA & EU Compliance

Safeguards Reputation

Saves Costs

Speak to our Team of Experts

UK TEL +44 (0) 118 936 4400 | US TEL +1 508-948-6100  
 prisymid.com | info@prisymid.com