MEDICAL DEVICE LABEL: BEFORE AND AFTER EU MDR/IVDR

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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.

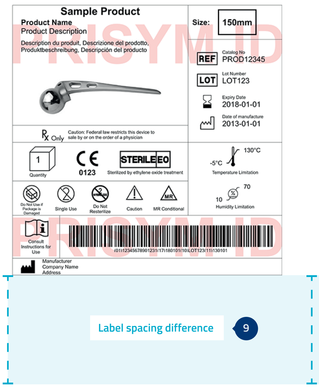
07 Include reprocessing cycles
This is another huge data challenge. Under EU MDR, labels for single-use devices that can be reprocessed must detail the maximum amount a device can be reprocessed as well as the number of times the individual device has been reprocessed to date.

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.

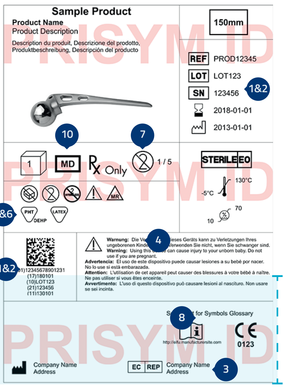
09 Label spacing differences
In order to address the fact that new mandatory content – such as the addition of warning & precautions (see #4) – is almost certainly going to create congestion, the recent Final Ruling by the FDA no longer requires English text to appear alongside symbols in order to free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



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

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