Are Your Labels EU MDR Ready?

Labeling Impacts of the New European Medical Device Regulation
Presenter

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- B.S. Mechanical Engineering
- 15+ years in Medical Device Industry
Agenda

› History & Background
› Label Content Changes
› UDI & EUDAMED
› IFUs & Patient Implant Cards
› Key Dates
› How Can QTS Help?
What follows is based on the presenter's personal and QTS' collective knowledge regarding EU MDR, UDI and EUDAMED requirements. QTS is not a supplier of regulatory services or advice.

The intent of this presentation is to share our interpretation and best practices with our Customer partners. You are strongly encouraged to research and implement these regulations and guidance in a manner supported by your Quality System(s) and Regulatory resources.
History & Background
Background

Where We Were: Medical Device Directive (MDD)
- Official: June 14, 1993
- Several amendments, most recent in 2007

Where We Are Going: Medical Device Regulation (MDR)
- Official: April 5, 2017
- Supersedes the MDD
Renewed Focus on Users

- Technical Knowledge, Experience, Education, Training
- Readily Understood by the Intended User

<table>
<thead>
<tr>
<th>MDD</th>
<th>MDR</th>
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<tbody>
<tr>
<td>13.1 Each device must be</td>
<td>23.1(a) The medium, format, content, legibility, and location of the</td>
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<tr>
<td>accompanied by the information</td>
<td>label and instructions for use shall be appropriate to the particular</td>
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<tr>
<td>needed to use it safely and</td>
<td>device, its intended purpose and the technical knowledge, experience,</td>
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<tr>
<td>properly, taking account of</td>
<td>education or training of the intended user(s). In particular,</td>
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<tr>
<td>the training and knowledge</td>
<td>instructions for use shall be written in terms readily understood by</td>
</tr>
<tr>
<td>of the potential users…</td>
<td>the intended user and, where appropriate, supplemented with drawings</td>
</tr>
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<td></td>
<td>and diagrams…</td>
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</table>
Renewed Focus on Safety and Transparency

- Device safety and clinical effectiveness data is required to be transparently shared with users via EUDAMED and Instructions for Use (IFUs)

- Safety and Effectiveness is Paramount
  - Device certification through equivalency has become more rigorous
  - Data is required for all submissions
Label Content
Changes
Label Content Changes

- Name or Trade Name of the Device
- Manufacture Date (if no Expiration Date)
Label Content Changes

- Indication that the device is a Medical Device
- Warnings or Precautions that need to be brought to the immediate attention of the user
- eIFU
  - Add Web Address

Amazing Fixation
Coated 14mm Fixation Screw

Not an internationally recognized symbol
Label Content Changes

- Explicit Requirements for Sterile Barrier Labeling
  - Identification the sterile barrier
  - Declaration of the Sterile Condition (e.g. Sterile, Non-Sterile)
  - Sterilization Method
  - Manufacture Date (Month & Year)
  - Expiration Date (Month & Year)
  - Directive to check IFU if package appears damaged

Amazing Fixation Coated 14mm Fixation Screw

Not an internationally recognized symbol
Label Content Changes

- Absorbed Materials
  - Overall composition for absorbed devices and quantitative information on the main constituent(s)

Amazing Fixation Coated 14mm Fixation Screw

Not an internationally recognized symbol
**Items Not Applicable to our Label**

- Number of times a single-use device has been reprocessed
- Serial Number is required for all active implantables
Items Not Applicable to our Label

- Specific warning for devices including substances that are:
  - Carcinogenic
  - Mutagenic
  - Toxic to reproduction
  - Endocrine-disrupting properties

- Indication that the device contains tissue or cells of animal or human origin
Unique Device Identification
UDI = Unique Device Identification

- Very similar to the US FDA rule
- Unique identifying “part numbers” issued by a neutral party; assigned to your finished products
- Product packaging must be labeled with the UDI
- Some products must bear the UDI on the product itself (Direct Part Marking)
- UDIs must be registered in a database (EUDAMED)
Why UDI?

• Required to place a unique identifier
  – Non-partial agency
  – On packages and sometimes products

• Required to place certain production information
  – Machine-readable form

• Why do we do this?
  – Serves as the “primary key” of the regulatory database
  – Part numbering scheme may be the same as another
Designated Issuing Agencies
Composition of a UDI Symbol

Device Identifiers + Production Identifiers = UDI

(01)10123456789125
(17)000101
(10)0000DDDDYYzxx

Device Identifiers
Production Identifiers
Composition of a UDI Symbol

Device Identifier:
• Version or model of the device
• Labeler of the device
• Package quantity (unit of sale, multi-pack, etc.)
• Issued by your agency
Composition of a UDI Symbol

Production Identifier:
- Conditional, Variable
- Identifies the following IF included on the Device Label
  - Lot/Batch Number
  - Serial Number
  - Software Identification
  - Expiration Date
  - Manufacturing Date (if no expiration date)
• Label of the Device and all Higher Levels of Packaging
  – Primary package of the device
  – Multi-pack sales units
    ✓ *Does NOT include shipping containers*

• Reusable Devices
  – Device itself must be marked
  – Remain throughout the intended lifetime of device
    ✓ *Some exclusions*
What is EUDAMED?

- European Databank on Medical Devices
- Currently exists, and use has been mandatory for use since 2011
- MAJOR overhaul for MDR
- Planned Launch Date of March 25, 2020
MDR / EUDAMED / UDI Structure

EUDAMED
European MD/IVD Database

CERTIFICATES
- Issued
- Suspended
- Withdrawn
- Refused
- Restricted

VIGILANCE
- Serious Incidents
- FSCA
- FSN
- Corrective Actions

CLINICAL INVESTIGATION
- Sponsor
- Purpose
- Status
- Approval
- Summary

MARKET SURVEILLANCE
- Measures taken by MS
- Preventative health measures
- Non-compliant devices

UDI Registration for Devices
Registration of Manufacturers and Economic Operators
Instructions For Use
IFU Changes

• Many Changes:
  – MDD has 17 sub-sections, MDR has 28 sub-sections
  – MDR sub-sections are much more descriptive

• Highlights:
  – Specification of the expected clinical benefits
  – Links to data on clinical performance and safety (EUDAMED)
  – Special training and/or facilities required to use the device
  – Information on the correct installation, operation and maintenance of the device
  – What to do if the sterile barrier appears damaged
  – Information on the reuse of single-use devices
  – Expanded requirements for warnings to the users
Patient Implant Cards

• New Requirement; Only Applies to Implants

• Required Info
  – Device Name
  – Serial Number and/or Lot Number
  – UDI
  – Device Model
  – Manufacturer Name, Address & Website

• Health Institutions Required to Provide Rapid Access to Additional Information

Patient Implant Card

Amazing Fixation
Coated 14mm Fixation Screw

REF
ABC123
LOT
1234DDDYzxx

Amazing Fixation Inc.
1000 Roadrunner Road
Minneapolis, MN 55438
www.amazing-ifu.com

(01)10123456789125
(17)000101
(10)0000DDDYzxx
## Key Dates

<table>
<thead>
<tr>
<th>WHEN</th>
<th>WHAT</th>
<th>NOTES</th>
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<tr>
<td>November 2017</td>
<td>Notified Body designation process begins</td>
<td>EU pares down the list of approved organizations for accepting and certifying products</td>
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<td>May 26, 2020</td>
<td>All device certifications and recertifications must be performed under MDR</td>
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<tr>
<td>May 26, 2022</td>
<td>All certifications and recertifications must be performed under IVDR</td>
<td></td>
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<tr>
<td>May 26, 2024</td>
<td>All MDD and IVDD certificates become void.</td>
<td>Any medical devices or IVDs to be sold must have MDR/IVDR certificates.</td>
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<tr>
<td>May 26, 2025</td>
<td>All medical devices and IVDs put into service, must have MDR/IVDR certificates.</td>
<td>Nothing certified under the old system can be used for the first time.</td>
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</table>
How can QTS help you succeed?

Expertise
• GS1 and HIBCC barcodes
• Label symbology updates

Industry Partners
• IFUs and printed content

Cretex Medical Partners
• Direct Part Marking
Connect with QTS:

- Contact your QTS Account Manager
- Email: info@qtspackage.com
- Online: qtspackage.com
- Phone: 952.942.8321
- Social Media:
Resources & References

- GS1 Website (www.GS1.org)
- GS1 Guide on Unique Device Identification (UDI) implementation in the USA and in the EU (https://www.gs1.org/sites/default/files/docs/healthcare/position-papers/gs1_udi_guide_final_20170324.pdf)
- Health Industry Business Community Council (HIBCC) Website (www.HIBCC.org)
- International Council for the Commonality in Blood Banking Automation (ICCBBA) Website (www.iccbba.org)
- QTS Resources Page (https://qtspackage.com/medical-device-resources/)
Thank You.

Quality Tech Services, LLC

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