Content Requirements under MDR

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Introducing the Qserve TEAM !!

• Experts in Regulatory | Quality | Clinical affairs | Market access
  • “One-stop shopping”
• 100% medical devices
• Medical Doctors on Staff
• High level of expertise (many former NB, FDA and CFDA)
• Global reach (offices in Europe, USA and China & partners worldwide)
• Full-service CRO
• Native Speakers in >10 languages
Information Supplied with the Device
Label and Instructions for Use (GSPR 23)

1. General Requirements
2. Information on the Label
3. Information on the Packaging which maintains the sterile condition of the device (“sterile packaging”)
4. Information on the Instructions for Use
General Requirements (GSPR 23.1)

• Information to identify device, manufacturer, safety and performance information
  • Device OR packaging OR IFU; AND
  • Website
Label: New Requirements (23.2)

- UDI
- “an indication that the device is a medical device”
- Hazardous substances
- Indication device contains medicinal substance and substances of human and animal origin
- Specific requirements for single-use reprocessed devices and ‘substance based medical devices’.
Sterile Packaging (23.3)

- Details requirements for sterile packaging – most requirements not new

- “an indication permitting the sterile packaging to be recognized as such” .. Sterile symbol enough? Sterile “dot”?  
  - Key is can recognize the sterile barrier (e.g. when double pouched)

- Check IFU for instructions if damaged or unintentionally opened before use
IFU: New Requirements

• Clear specification of patient target groups, indications, contra-indications, intended users
• Requirements special facilities, training, qualifications
• Clinical benefits expected
• Link to Summary of Safety and Clinical Performance (implantable, III)
• Hazardous substances
• Disposal (test method!)
• Serious incidents reported to manufacturer and CA
IFU: New Requirements

- Reusable devices: identify when device should no longer be reused
- Substance-based medical devices: interactions and overdose risks
- **Implantable devices**: qualitative and quantitative information on materials and substances
- Lay user devices: when to consult a healthcare professional
- No medical purpose: information on absence of clinical benefit and risks
- Electronic Programmable Systems: minimum IT requirements
Article 18 – Implant Card

1. On card AND website
   • Device name, serial #, lot # (can we use a sticker? EC not in favour), UDI, model, name, address and website of MFR

2. “by means allowing rapid access”
   • Warnings, precautions etc re reciprocal interference with external influences, medical exams, environment
   • Expected lifetime of device and necessary follow-up
   • Info on materials/substances to which patient can be exposed

3. In national language

4. Understandable by lay person
Symbols

• EN ISO 15223-1:20XX
  • Harmonized to MDR – when?

• MedTech Guidance document
  • Validated symbols per ISO 15223-2

  • Also includes symbols for use in implant card

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Use of Symbols to Indicate Compliance with the MDR
May 2019

The Medical Devices Regulation 2017/745/EU (‘MDR’) has new requirements that ask for various kinds of information to be indicated on the label of medical devices. To comply with this requirement within the short term and in a harmonised manner, before the international standard is available, MedTech Europe publishes the present guidance on symbols for the following information:

1. Medical device
2. Contains human blood or plasma derivatives
3. Contains a medicinal substance
4. Contains hazardous substances
5. Contains biological material of human origin
6. Contains biological material of animal origin
7. Sterilized using vaporized hydrogen peroxide
8. Translation
9. Repackaging
10. Single Patient Multiple use

Additionally, in Annex 2 of the present guidance MedTech Europe recommends symbols to be used with patient implant card.
Language Requirements (Article 10) - general

• Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.
Language Requirements - TD – Annex II, 2

• TD to include ...

• “A complete set of:
  • the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold; and
  • The instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.

Technical documentation

• It is sufficient to show information concerning labelling in English only, but items to be translated and the plan for translation should be indicated.
SSCP – two versions in some cases

- Art. 32(1) requires SSCP SHALL be written in a way that is clear to the intended user and, if relevant, to the patient
  - This implies a different literacy levels when intended for healthcare professionals (HCP) and patients, respectively
  - Hence **TWO versions** of SSCP!
    - One for HCP
    - One for patients!
Language requirements - SSCP

• The version of the SSCP uploaded to Eudamed should be:
  1. Protected against modification;
  2. Readily searchable (when downloaded);
  3. Readily printable (when downloaded).

• SSCP should be **TRANSLATED** into the languages of all MS where it is envisaged device will be sold (similar to IFU);
  • Version for the patient, **one language per document**!

• Template/guidance for SSCP in the **CIE document**
SSCP for the Patient ...

• Written in clear, concise language
• Medical terms should be explain in simple language
• 12 point font
• Written at level 2-3 in International Adult Literacy Survey
  • Somewhere between “understandable by a 12yo” and “high school completion” level

• (further guidance in CIE document and related references)
Getting it to Eudamed …

1. **Submit** SSCP as part of packet of info to NB for Conformity Assessment
2. Once they have issued the CE certificate, **NB upload to Eudamed WITHIN 30 DAYS**
3. NB will validate the SSCP submitted meets all requirements of Art 32 (content) and is consistent with TD submitted
4. NB will validate BOTH the version for HCP and PATIENTS
5. NB will **only validate** in the languages accepted by that NB or accepted in their MS
   - Hence MFR will have to translate and VALIDATE the other languages in analogy with process for IFU
Connection with eIFU Regulation
COMMISSION REGULATION (EU) No 207/2012
of 9 March 2012
on electronic instructions for use of medical devices
(Text with EEA relevance)

Article 1

This Regulation establishes the conditions under which the instructions for use of medical devices referred to in point 15 of Annex 1 to Directive 90/385/EEC and in point 13 of Annex I to Directive 93/42/EEC may be provided in electronic form instead of in paper form.

It also establishes certain requirements concerning instructions for use in electronic form which are provided in addition to complete instructions for use in paper form relating to their contents and websites.
When can we use just eIFU?

Article 3

1. Subject to the conditions set out in paragraph 2, manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to any of the following devices:

(a) active implantable medical devices and their accessories covered by Directive 90/385/EEC intended to be used exclusively for the implantation or programming of a defined active implantable medical device;

(b) implantable medical devices and their accessories covered by Directive 93/42/EEC intended to be used exclusively for the implantation of a defined implantable medical device;

(c) fixed installed medical devices covered by Directive 93/42/EEC;

(d) medical devices and their accessories covered by Directives 90/385/EEC and 93/42/EEC fitted with a built-in system visually displaying the instructions for use;

(e) stand-alone software covered by Directive 93/42/EEC.

2. Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions:

(a) the devices and accessories are intended for exclusive use by professional users;

(b) the use by other persons is not reasonably foreseeable.
What do we have to do?

- Risk Assessment
- Use electronic form of IFU in all Member States
- Provide in paper form on request by user (no cost to them; within 7 calendar days)
- System to inform users of revisions
- Provide info on how to access the electronic form of the IFU
- Website (if used) shall be:
  - Protection against hardware/software intrusion
  - Server downtime and display errors reduced as far as possible
- ........
And if we provide eIFU (e.g. website) as well as paper ... 

Article 9

Instructions for use in electronic form which are provided in addition to complete instructions for use in paper form shall be consistent with the content of the instructions for use in paper form.

Where such instructions for use are provided through a website, this website shall fulfil the requirements set out in points (b), (e) and (g) of paragraph 2 of Article 7.

1. Protected against hardware and software intrusion ("cybersecurity")
2. Meet GDPR
3. All previous versions of eIFU (and publication date) to be on website
Promotional Material
Claims (Article 7)

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device’s intended purpose, safety and performance by:

(a) Ascribing functions and properties to the device which the device does not have;

(b) creating a false impression regarding treatment for diagnosis, functions or properties which the device does not have;

(c) Failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;

(d) Suggesting uses for the device other than those state to form part of the intended purpose for which the conformity assessment was carried out.
## Example “Claims Matrix”

<table>
<thead>
<tr>
<th>Product</th>
<th>Document Reviewed</th>
<th>Unique claim #</th>
<th>(Unique) Claims (per document)</th>
<th>Objective Evidence</th>
<th>Is Clinical Evidence needed to demonstrate claim?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>A self-adhesive cement specifically formulated for excellent handling properties and easy clean-up</td>
<td>Design V&amp;V test in PD-01011</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td>Radiopaque material is easily identified on radiographs</td>
<td>Design Verification test in PD-01011 Per ISO 4049</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>Low film thickness ensures the restoration is completely sealed</td>
<td>Design Verification test in PD-01011 Per ISO 4049</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4</td>
<td>A cost effective alternative designed to bond to a multitude of substrates, including metals, composites, porcelain and amalgam</td>
<td>Design Verification test in PD-01011 per QC Testing procedure, Cost estimate is in PD-01011 In Marketing Plans.</td>
<td>No</td>
</tr>
<tr>
<td>Product A</td>
<td></td>
<td>5</td>
<td>Glass ionomer benefits with resin cement strength</td>
<td>R&amp;D Project Status Report, RDQSP-04-03 in PD-01011</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6</td>
<td>No etching, priming or bonding saves time by reducing clinical steps</td>
<td>Compared to total etch, Design Verification test in PD-01011 per QC Testing procedure (Bond strength)</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7</td>
<td>An auto-mix dual-syringe delivery requires no hand mixing that can be dispensed directly into the restoration</td>
<td>Packaging DMR, PK5110 (This is a purchased item from Mixpac – verified in usability testing) Yes Design Validation in PD-01011</td>
<td>No</td>
</tr>
</tbody>
</table>

**NOTE:** Of course, clinical evidence can be used in support of all claims; all claims can be challenged if PMES data is not supportive.
Article 21(3)

- At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create obstacles to the showing of devices which do not comply with this Regulation, provided a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been brought into compliance with this Regulation.
Article 20(5) – CE Marking

• Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 52. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

• Complete reverse of MDD (i.e. now including CE in promotional material, in some circumstances)!
New PMS content
Connection between QMS processes and various plans/report

- PMS Report (as necessary)
- PSUR (≤1yr for class III and IIb; ≤2yr for IIa)
- Revise PMS Plan?
- Optionally, update RMR #3?
- Update RMF?
- Update RMP?
- (e.g. RAC)?
- Update CER #4
- Update SS&CP (≤1yr for class III implants) #5
- (Revise CEP?)
- Gather PMS/PMCF data #1
- PMCF (Process) Report #2
- (≤1yr for class III implants)

1st time round cycle

PMCF

>1st time round cycle

PMF
A note on Resources ...
Back of the envelope estimates JUST FOR THESE PLANS/REPORTS (MDR ONLY) (not including Supply Chain, IT, Vigilance, UDI, Legal, 13485:2016, MDSAP ...)

N = # of TF/CER

• Remediation
  • CER updates = 30 x N = 30N days
  • PSUR creation = 20 x N = 20N days
  • PMCF report = 10 x N = 10N days
  • SS&CP creation = 15 x N = 15N days
  • TF remediation = 7 x N = 7N days
  • TOTAL = 82N days
    • N=1, 82 days (≈ 0.4 FTE)
    • N=10, 820 days (≈ 4 FTE)
    • N=100, 8200 days (≈ 40 FTE)

• Maintenance
  • CER updates = 10 x N = 10N days
  • PSUR revisions = 10 x N = 10N days
  • PMCF revisions = 5 x N = 5N days
  • SS&CP revisions = 3 x N = 3N days
  • RMR revisions = 1-5 x N = 1N-5N days
  • TF maintenance = 1-3 x N = 1N-3N days
  • TOTAL = 30N – 36N days
    • N=1, 30-36 days (≈ 0.15 to 0.18 FTE)
    • N=10, 300-360 days (≈ 1.5 to 1.8 FTE)
    • N=100, 3000-3600 days (≈ 15 to 18 FTE)

Assume 1 FTE = 200 days
Vigilance and FSCAs
Vigilance Reportability

• Any serious incident involving devices made available on the Union market
  • Serious incident includes temporary or permanent serious deterioration of health

• Any field safety corrective action for devices made available on the Union market, including field safety corrective actions in third country

• Reports submitted to EUDAMED
May get same complaint several times ...
Thank you for your attention

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