THE MDR JOURNEY

NEWSLETTER No. 21 – January 2021

«Let's make transparency a standard requirement»

Subject:

Moving from the MDD to the MDR - Sterile CPTs – Usability

As compliance with the 'Essential Requirements (ERs)' is the keystone for establishing conformity with the Medical Device Directive (MDD, 93/42/EEC), so too is compliance with the 'General Safety and Performance Requirements (SPRs)' in establishing conformity with the Medical Device Regulation – EU Regulation 2017/745 (MDR).

In the new MDR, the overall text and requirements are expanded. Usability now has increased emphasis and more explicit requirements, which align with harmonized standards and industry guidance. Importantly, all of these points will now become European law under this Regulation. **As highlighted in the previous Newsletter No.20 the area of labeling requirements in Annex I, has a high impact on manufacturers**.

MDD Annex I Essential Requirement (ERs)

ER 1 acceptable risks when weighed against the benefits to the patient

Shall include:

— reducing, as far as possible, the risk of use error due to the **ergonomic features** of the device and the environment...

— consideration of the technical knowledge, experience, education, and training and where applicable the medical and physical conditions of intended **users** (design for a lay, professional, disabled, or other users)…

ER 9.2 the risk of injury, in connection with physical features, including ergonomic features…

ER 10.2 The measurement, monitoring, and display scale must be designed in line with ergonomic principles

ER 13.1 Device accompanied by the information needed to use it

• safely and properly,

• taking account of the training and knowledge of the potential users

Other ERs that may be affected include 2, 3, 6, 12.8, 12.9

MDR – Usability in Definitions – articles

'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken;

'device deficiency' (new) includes use errors or inadequacy in the information supplied by the manufacturer

'**incident**' (new) includes use-error due to ergonomic features, as well as any **inadequacy in the information supplied by the manufacturer**

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Article 83 Post-market surveillance system of the manufacturer

PMS system data shall, in particular, be used for the identification of options to **improve the usability**, **performance, and safety** of the device

Other Art. that are affected include:

Article 32 Summary of safety and clinical performance

Article 61 Clinical evaluation

Article 62 General requirements regarding clinical investigations conducted to demonstrate conformity of devices

MDR Annex I General Safety and Performance Requirements (SPRs)

SPR 5 In eliminating or reducing risks related to **use error**, the manufacturer shall: (a) reduce as far as possible the risks related to the **ergonomic** features of the device and the environment in which the device is intended to be used (design for patient safety), and (b) consider the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of **intended users** (design for a lay, professional, disabled or other users). Similar to **MDD ER 1**

SPR 14.2 Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate **ergonomic** features. Similar to **MDD ER 9.2**

SPR 14.6 Any measurement, monitoring, or display scale shall be designed and manufactured in line with **ergonomic** principles, taking account of the intended purpose, **users,** and the environmental conditions in which the devices are intended to be **used**. Similar to **MDD 10.1**

SPR 21.3 The function of the controls and indicators shall be specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters using a visual system, such information shall be **understandable to the user** and, **as appropriate, the patient**. Similar to **MDD 12.9**

SPR 23.1 Each device shall be accompanied by the **information** needed to identify the device and its manufacturer, and by any safety and performance information relevant to the **user, or any other person, as appropriate**… Similar to **MDD 13.1**

SPR 20.5 Removable and moving parts. Fitting/refitting risk made **impossible** by the design and construction…Direction of movement information

SPR 22 Medical Devices for a **layperson**. Take account of **their skills**. Information/instructions provided shall be easy for them to understand/apply

SPR 22.2 Devices for use by a **layperson.** The device can be used safely and accurately by the intended user. Reduce risk from unintended cuts and pricks e.g. needle stick injury. Reduce handling errors and interpretation of results.

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Annex III Post Market Surveillance

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

(f) for the identification of options to improve the **usability, performance, and safety** of the device;

Usability requirements included in EN ISO 13485: 2016:

7.3.3a design and development inputs - Include **usability requirements** according to the intended use
7.3.9 control of design and development changes - Consider the **significance of a change to usability**

ISO 11607-1:2019 define:

sterile barrier system as a minimum package that prevents ingress of microorganisms and allows the aseptic presentation of the product at the point of use

the aseptic presentation as an introduction and transfer of a sterile product using conditions and procedures that exclude microbial contamination

But what does it mean aseptic technique and aseptic presentation?

Surgical aseptic technique means "sterile technique" used for invasive procedures including minor surgical procedures that may be performed in a community health care setting such as cataract removal; biopsies; laparoscopy; hernia repair, dental implants, and foot surgery. The goal of surgical aseptic technique is to maintain the microbial count to a minimum using sterile medical device; practices such as surgical hand scrub and patient skin antisepsis; and barriers including sterile gloves, sterile gown, masks, and sterile drapes to prevent transferring microorganisms for the environment to the patient during the procedure.

A sterile field is created following local applicable procedures, typically with a sterile drape over a table to place the sterile products onto before they are used during a procedure. It is important to protect the unpacked, exposed device from microbial contamination through breathing, talking or the shedding of particles and micro-organisms originating from the skin of personnel when reaching over the device. Excessive movement in the area should be avoided and the time of exposure before the device is used should be minimized.

Aseptic presentation now becomes a more explicit requirement SPR 11.1 and SPR 23.3:

SPR 11.1 Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users, and, where applicable, other persons. The design shall:

(b) **allow easy and safe handling**,

(d) **prevent microbial contamination** of the device or its content such as specimens or fluids.

The general intent of SPR 11.1 corresponds to MDD ER 8.1, with additional specificity.

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SPR 23.3 Information on the packaging which maintains the sterile condition of a device ('sterile packaging')

The following particulars shall appear on the sterile packaging:

a) an **indication permitting the sterile packaging to be recognized as such**,

The separation of requirements for the sterile package label (as opposed to simply the device label) is new in SPR 23.3 in comparison to the MDD, but the requirements are similar.

Usability aspects of sterile barrier systems shall be considered in the context of the clinical environment when designing a sterile barrier system and when defining the way the product(s) is (are) positioned in the SBS. Usability evaluations should be conducted to verify that the design meets the design criteria.

This newsletter is part of our campaign to increase the sensitivity and the awareness of all our business partners, to bring more clarity around the MDR journey and challenges and opportunities around the MDR Art.22 "Systems and Procedure Packs".

We are already today all dependent on effective cooperation. For the MDR implementation, we require even closer collaboration to ensure we all can deliver safe supply to hospitals and patients in the future.

We are confident we'll be able to continue to supply health care competently on customized surgical procedure sets and small kits.

Do you want to know more about specific topics? Do you have any questions or comments?

Write to us *MDR2020@stsmedicalgroup.com*

The next MDR Newsletter will be issued in February. We wish everybody pleasant days.

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