THE MDR JOURNEY

***NEWSLETTER No. 7 – October** 2019*

«Let's make transparency a standard requirement»

Subject: What is the Intended Use?

Intended Purpose vs. Intended Use

In the last newsletter regarding the Procedure Packs, a check of the mutual compatibility and in particular regarding the compatibility of the intended use was mentioned. This raises the question what is the meaning of "intended use" and why is this "intended use" important both for manufacturers and users.

First, we need to find the definition of intended use. This term is not in the definition of the MDR where we can just find the term "Intended Purpose". The MDR definition of an Intended Purpose is "…the use for which a device is intended…" according to the labeling (Label, Instruction for Use, etc.).

Just a simple example: For cannula, which is used for blood taking a purpose might be defined as "to puncture the skin and channel blood during blood taking". In this case, the Intended Purpose is the medical activity to achieve or support a medical goal.

However, is it sufficient to define just the medical purpose of the device?

The medical purpose answers the questions for "what" is the device good for. Of course not, but what else is needed? If we read carefully into the MDR we can recognize that the wording "intended use" is also often used.

Although the term is not defined, it is often used in the context of Risk Management and within the used context, it seems that the medical purpose is not the only relevant part.

In order to identify a proper answer we have to look into the Risk Management Standard EN ISO14971. There we can find guidance in Annex C regarding how to define the intended use of a medical device.

In this Annex, the intended use is defined as the purpose in achieving a certain medical goal in combination with the indication e.g. the patient population and the user population.

Patient population describes which patients are suitable to be treated with the medical device, where the user population defines the knowledge and experience a user should have.

Also the usability has to be taken into account. Again, we can find some guideline in Chapter 5 of EN 62366.

The usability standard extends the intended use by:

- the medical indication,
- part of body subject to the medical treatment,
- intended conditions of use.

Other questions to answer to define an intended use are:

- What is the medical Purpose and when is the medical application indicated?
- Who is the patient population (e.g. age, size, weight)?
- Who will use the product (e.g. lay user, nurses and physicians)?
- Where the product is used?
- Which conditions are intended for use (sterile device, single use, multiple use, temperature limits, light conditions, duration of application, shelf life)?

Therefore, going back to the example introduced in the beginning, it is a must to address this information to get a complete clarification about the intended use.

Once the intended use is clearly defined, there is still the problem that we clarify the definition of Intended Purpose. This issue is resolved by the Risk Management Standard EN ISO 14971 where the intended use is defined as … the Intended Purpose!

The term of the "intended use" is commonly used in the US whereas the term "intended purpose" is more common in the European Union.

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Why is an intended purpose needed?

The intended purpose is required for manufacturers because it is a starting point of many parallel processes, in-fact as a medical device the intended purpose will develop during the development progress of the device.

After the "development" of the Intended Purpose", , the manufacturer has a good insight in which conditions and indications the device can be used by user groups on alternative user populations to achieve a certain medical purpose.

Based on the above, the manufacturer declares the conformity of a product and "certifies" that for the specified intended purpose the medical device is safe and effective and the usage does not lead to an unacceptable risk to the patient or the user.

Of course the intended purpose is not only of interest for the manufacturer.

The MDR requires that the intended purpose is provided to the user in the accompanying documentation, like the labels and the instructions for use.

As a user, do I have to follow the Intended Purpose?

From the perspective of a user this limitations might not be obvious. Therefor the user has to act on:

- this intended purpose
- and according to the manufacturer's instructions.

Using the medical device in a different way – the so-called off-label use – may lead to an increased patient risk and liability risk for the user.

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 arising from the definition of an Intended Purpose.

We are already today all dependent on an effective cooperation. For the MDR implementation, we require even a closer collaboration in order 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.

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You want to know more about specific topics? Do you have any questions or comments? Write us MDR2020@stsmedicalgroup.com

The next MDR Newsletter will be issued in November. We wish everybody a pleasant golden autumn day.

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