THE MDR JOURNEY

NEWSLETTER No. 8 – November 2019

«Let's make transparency a standard requirement»

Subject: Risk Management

Introduction

In the last Newsletter, we were talking about the definition and the intention of an Intended Purpose. This Intended Purpose is the base of the Risk Management activities conducted for a Medical Device. To understand the concepts of the Risk Management activities it is important to understand the meaning of risk.

What is a Risk?

In the Risk Management Standard EN ISO 14971, a risk is defined as the "combination of the probability of occurrence of a harm and the severity of that harm". The probability of occurrence is a measure for the likelihood that a harm occurs.

The severity of a harm is clustered into several grades. Examples of the harm seriousness may be:

- "temporary" for skin irritations,
- "permanent impairment" for a permanent damage to an organ or a part of the body,
- or in worst case resulting in "death".

Based on the Intended Purpose, the expected Clinical Benefit, the defined probability and severity levels a manufacturer of medical devices has to decide which risks are acceptable and which are not. The decision is documented in the risk management plan and may have the form of a risk chart as displayed below.

Probability Occurrence of Harm					
	O4	AC	IN	IN	IN
	O3	AC	AC	IN	IN
	O2	AC	AC	AC	IN
	O1	AC	AC	AC	AC
		S0	S1	S2	S3
		SEVERITY of HARM			

In this simplified Risk Graph the Probability is given by O1-O4 and the Severity by S0-S3.

AC means acceptable and **IN** means intolerable. A medical device with an Intolerable Risk cannot be made available on the market.

What is a "Hazardous Situation"?

To evaluate a Risk it is also important to identify where this risk might occur. This situation is named the "Hazardous Situation". A Hazardous Situation is the relationship between the medical process to perform and a malfunction or a wrong usage of the Medical Device.

As an example:

- The skin has to be punctured by a needle,
- The needle is blunt,
- The user cannot puncture the skin.

How is the evaluation of a risk done?

To evaluate a Risk of a Hazardous Situation it is important to know the purpose of the medical procedure. If the needle of the previous example, it is just used for "blood taking" it makes a lot of different in the two alternative situations described below:

- during a standard examination
- or if the needle is used during an emergency to deliver life savings medicines

If a Medical Device can be used for several purposes, a manufacturer has to take all of the purposes covered by the Intended Purpose into account and has to ensure that the Medical Device is safe and effective in any of these purposes.

How can risks be mitigated?

The Risk Management Standard EN ISO 14971 and the MDR allow the reduction of a risk. To reduce a Risk the manufacturer has four options:

- Inherent safety by design or manufacturing,
- Protective measure,
- Information of Safety,
- Restriction of the Intended Purpose.

After the Risk Mitigation, the Risk needs to be evaluated again, aiming to mitigate the Risk to its best.

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Importance of the information from the Market.

For a new medical device it is not easy to determine the probability of a Hazardous Situation. In most cases, it is an assumption based on experience from comparable products and scientific data.

This assumption needs to be compared and evaluated (by who?).

For this reason, the information collected via the Post Market Surveillance and Vigilance Tools (which was part of one of the previous Newsletters) are used to analise the alternative possible scenario and to ensure that all occurring hazardous Situations are evaluated and described in the Risk Management File accordingly to the resulting risks.

So, reducing risks for the benefit of patient and users is one of the main reasons the MDR is strengthening the focus on post market surveillance, trend reporting and vigilance processes in connection with the risk management.

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 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.

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

If you want to rewiew previus pubblished MDR newsletter use below link: http://www.stsmedicalgroup.com/the-mdr-journey-2/

The next MDR Newsletter will be issued in December.

We wish everybody pleasant days.

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