THE MDR JOURNEY

«Let's make transparency a standard requirement»

NEWSLETTER N. 40 – Dec 2023

Subject: Improvement in the context of MDR

As introduced in November's newsletter, Regulation (EU) 2017/745 on medical devices (MDR) establishes general obligations of manufacturers with respect to the quality management system (QMS). On article 10.9(m), special mention is made to the manufacturer's obligation to have in place processes for monitoring and measurement of output, data analysis and product improvement.

In the same line, EN ISO 13485:2016 standard entitled Medical Devices – Quality management systems – Requirements for regulatory purposes, has a full section (section 8) dedicated to measurement, analysis, and improvement.

In this newsletter edition, we are taking a closer look at how manufacturers fulfil their obligations on improvement.

Which is the purpose of improvement?

Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with MDR in the most effective manner that is proportionate to the risk class and the type of device.

How is improvement managed?

According to ISO 13485:2016, the organizations shall identify and implement any changes necessary to ensure and maintain:

1. the continued suitability, adequacy and effectiveness of the QMS

2. as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review.

Each of these QMS processes provides data or defines the actions to systematically achieve device and/or QMS improvements.

In turn, MDR places special emphasis on change management as a means of keeping up to date with the state of the art. In this sense, regulatory intelligence process takes on vital importance.

According to MDR Article 10, Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of MDR. Changes in device design or characteristics and changes in the harmonized standards or common specification by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner.

What is the role of the distributors?

While product and QMS improvement are one of the responsibilities of the manufacturer, distributors play an active role in providing information on product performance on the market, user demands and local requirements. Therefore, the more accurate is the information collected in the market, the more data the manufacturer will have available to generate improvements and the better the products and services for the distributor will become.

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 efficient cooperation. For the MDR implementation, we require even closer collaboration to ensure we all can deliver safe supplies to hospitals and patients in the future.

We are confident we will continue to supply health care competently on customized surgical procedure sets and small kits.

Do you wish to know more about specific MDR topics? Do you have any questions or comments about STS newsletter? Write us at MDR2020@stsmedicalgroup.com.

The next MDR newsletter will be issued in January.

We take this December release opportunity to wish everyone a warm, happy and wonderful holiday season and a great start for the new year 2024.

Augusto Orsini
CEO
STS Medical Group

Meritxell Laguna
Group Manager Regulatory Affairs
STS Medical Group

JOYEUX NOËL FROHE WEIHNACHTEN ВЕСЕЛА КОЛЕДА FELIZ NAVIDAD BUON NATALE FELIZ NATAL

Anche quest'anno STS Medical Group ha deciso di sostenere la Comunità Papa Giovanni XXIII che ogni giorno, in tutto il mondo, condivide la vita con le persone fragili ed emarginate. Con il nostro aiuto la Comunità potrà continuare a prendersi cura degli ultimi nelle proprie case e realtà di accoglienza e a garantire un pasto a chi ha perso tutto perché ritrovi la propria dignità e speranza nel futuro.

Once again this year, STS Medical Group has decided to support the Pope John XXIII Community, which shares its life with fragile and marginalized people around the world every day. With our help, the Community will be able to continue caring for the last ones in their homes and shelter realities and to guarantee a meal to those who have lost everything so that they can regain their dignity and hope for the future.

Wie bereits in den Vorjahren wird die STS Medical Group eine gemeinnützige Organisation unterstützen: Die „Comunità Papa Giovanni XXIII“ setzt sich für die Bekämpfung von Ausgrenzung und Armut ein. Die Mitglieder der Gemeinschaft teilen ihr Leben mit den Ärmsten und leben weltweit als Familie mit denjenigen zusammen, die sonst keine Familie haben.Mit unserer Spende helfen wir Menschen, dass sie ihre Würde und Hoffnung für die Zukunft wiedererlangen können.

Cette année, STS Medical Group a décidé de soutenir la Communauté du Pape Jean XXIII, qui accueille chaque jour sa vie avec des personnes fragiles et marginalisées dans le monde entier. Grâce à notre aide, la Communauté pourra continuer à s'occuper des derniers dans leurs maisons et refuges et à garantir un repas à ceux qui ont tout perdu afin qu'ils retrouvent leur dignité et l'espoir en l'avenir.

También este año, STS Medical Group ha decidido apoyar a la Comunidad Papa Juan XXIII, que cada día comparte su vida con personas frágiles y marginadas de todo el mundo. Con nuestra ayuda, la Comunidad podrá seguir ocupándose de los últimos en sus casas y albergues y garantizar una comida a quienes lo han perdido todo para que recuperen la dignidad y la esperanza en el futuro.