Usability Questionnaire

Intro and IFU

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INTRODUCTION

Dear MDM colleague,

We are happy that you accepted to take part in this questionnaire.

DuPont is a science company, committed to science-based innovation.

We work collaboratively to find sustainable, innovative, market-driven solutions to solve some of the world's biggest challenges, making lives better, safer, and healthier for people everywhere.

Within Tyvek® Medical Packaging, we continuously strive to engage with industry and academic partners to learn on subjects of interest around medical packaging (regulations, medical practice evolutions, etc).

IT ALL ABOUT PROTECTING THE PATIENTS

The Medical Device Regulation (MDR), adopted in April 2017, has introduced some changes and new requirements vs the MDD:

- MDR :
    - Requires to eliminate or to reduce as far as possible risk of Infection
    - Requires designs for this that prevent microbial Contamination
    - Requires that design of Medical Devices allows easy and safe Handling
    - Requires new Labelling and emphasises the need for new Symbols
    - Requires that SBS Integrity has to be evident for the final user
    - Requires that SBS be Sterile up "to the Point of Use", moving away from "until the protective packaging is damaged or opened"

As a consequence, packaging designs have to be more "user centric" and manufacturers have to consider packaging usability.

With the new MDR there will be more scrutiny by notified bodies, who will look at requirements versus available evidence in the technical documentation.

VALUE PROPOSITION

Objective of the survey:

With this questionnaire, DuPont intends to survey the Medical Device industry on their approach to package design Usability and Human Factors testing and evaluations.

This data would allow MDMs to:

- Assess their status vs industry common and best practices
- Assess their status vs regulatory changes
- Assess their status vs industry plans to comply with regulations

A SUMMARY OF THE RESULTS WILL BE SHARED WITH ALL PARTICIPANTS

INDIVIDUAL DATA will be handled with CONFIDENTIALITY AND ANONIMITY

GLOSSARY AND REFERENCES

For convenience, we list there the definitions of some key terms as outlined in some common standards:

USABILITY: characteristic of the USER INTERFACE that facilitates use and thereby establishes EFFECTIVENESS, EFFICIENCY and USER satisfaction in the intended USE ENVIRONMENT Note 1 to entry: All aspects of USABILITY, including EFFECTIVENESS, EFFICIENCY and USER satisfaction, can either increase or decrease SAFETY. (IEC 62366-1:2015)

USABILITY ENGINEERING: HUMAN FACTORS ENGINEERING, application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of MEDICAL DEVICES (including software), systems and TASKS to achieve adequate USABILITY Note 1 to entry: Achieving adequate USABILITY can result in acceptable RISK related to use. (IEC 62366-1:2015)

USER INTERFACE: means by which the USER and the MEDICAL DEVICE interact Note 1 to entry: ACCOMPANYING DOCUMENTATION is considered part of the MEDICAL DEVICE AND ITS USER INTERFACE. Note 2 to entry: USER INTERFACE includes all the elements of the MEDICAL DEVICE with which the USER interacts including the physical aspects of the MEDICAL DEVICE as well as visual, auditory, tactile displays and is not limited to a software interface. Note 3 to entry: For the purposes of this standard, a system of MEDICAL DEVICES can be treated as a single USER INTERFACE. (IEC 62366-1:2015)

ASEPTIC PRESENTATION: introduction and transfer of a sterile product using conditions and procedures that exclude microbial contamination (ISO 11607-1: 2006)

THANK YOU