HOW COPAN IS FACING THE EU MDR REGULATION

March 2021 -Update

The New Medical Device Regulation (MDR) came into force on the 25th of May 2017 and its application has been postponed to the 26th of May 2021.

Copan Group's Regulatory and Quality departments are committed to giving the best support to our customers and distributors in this transition.

Since the implementation date of the Reg. EU 745/2017 (MDR) is approaching, we would like to share some key points about Copan transition plan to MDR 745/17.

Given the importance and strategic impact of this regulation on our business, this update is intended to provide an overview on the current situation and the next steps:

Copan has obtained an extension of the validity of the current CE certificate under MDD 93/42/EEC to guarantee an extended transition period for marketability purposes. The CE certificate # G1 073936 0014 REV. 03, applicable to Copan Medical Devices class IIA is valid until May 2024.

Copan has established and implemented a quality plan to be compliant with the EU MDR requirements (e.g. Vigilance, Post-Market Surveillance, EUDAMED…) that will be in force from the date of MDR application.

Copan will maintain the current Notified Body TÜV SÜD for the CE marking process. TÜV SÜD has been designated for Reg. EU 745/2017 (MDR) and notified on NANDO as a Notified Body for MDR services on 22 May 2019.

The MD devices will be gradually CE marked according with MDR based on a transition plan agreed with the Notified Body.
FLOQSwabs® and CLASSIQSwab™ will be the first set of MDs certified in compliance with MDR. The transition is expected for Q2-2022. Copan will communicate the CE mark transition from MD to MDR, three months before the expected date. Transition to MDR of MD devices other than FLOQSwabs® and CLASSIQSwab™ will be gradually managed within CE certificate # G1 073936 0014 REV. 03 expiration of May 2024.

It's our priority to ensure the commercialization of our products in conformity with the EU Regulation, to provide the best products and services to our customers. With the extension of the current CE certificate, we guaranteed a continuous circulation of all our products throughout Europe until May 2024 without any interruption. For products for which you need to verify if they are covered by the extended CE certificate, please contact your customer service.

Elisabetta Zanella
Chief Regulatory Officer
COPAN ITALIA SpA