HOW COPAN IS FACING THE EU IVDR REGULATION

Brescia, March 2021

The New In Vitro Diagnostic Medical Device Regulation (IVDR) came into force on the 25th of May 2017 and its application has been set on 26th of May 2022.

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 2017/746 (IVDR) is approaching, we would like to share some key points about Copan transition plan to IVDR 746/17 given the importance and strategic impact of this Regulation on our business.

Copan IVD devices are currently CE marked as general/other IVD under self-declaration according with Directive 98/79/EC (IVDD). Based on the risk classification performed by Copan, **Copan IVD devices will be classified as CLASS A or CLASS A STERILE** (for devices provided as terminally sterilized) according with IVDR.

Copan is certifying the CLASS A STERILE devices with the Notified Body TÜV SÜD.
TÜV SÜD has been designated and notified on NANDO for Reg. EU 746/2017 (IVDR) services.

The transition from IVDD general devices to IVDR CLASS A and CLASS A STERILE devices will be managed within the date of IVDR application of 26th of May 2022.
Copan will communicate the CE mark transition from IVDD to IVDR, three months before the expected date.

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.
Please contact your customer service if you have any specific questions on this topic.

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