

Newsletter Advertisement

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Main

Regulatory Newsletter (EU)

by Michael Galliker, CEO of Regulatory Globe GmbH

Dear [FIRST NAME GOES HERE]

Please find below the latest news related to medical devices and in vitro diagnostic devices in Europe.

Main

- CHF 600.- / Week
- 100 words max.
- 1 Picture + webpage link
- 1 Action Button

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What else could be interesting:

EU Commission Report on reprocessing

Global Unique Device Identification Database (GUDID)

Team-NB: MDR Certification Process

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- CHF 200.- / Month
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Regulatory Newsletter (EU)

by Michael Galliker, CEO of Regulatory Globe GmbH

Dear [FIRST NAME GOES HERE]

Please find below the latest news related to medical devices and in vitro diagnostic devices in Europe.

Main

MDCG 2024-15: Clinical investigation reports and their summaries in the absence of EUDAMED

The document provides guidance on the procedure for publishing clinical investigation reports and their summaries until EUDAMED becomes fully functional. It outlines the submission process, labeling, management, and storage of these documents in a publicly accessible CIRCADB directory.

Link to document

MDCG 2022-3 Rev.1: Verification of manufactured class D by NB

This document provides guidance to notified bodies to clarify their role and responsibilities in relation to samples of manufactured class D devices or batches of devices in accordance with Annexes IX and XI of the In Vitro Diagnostic Medical Devices Regulation (IVDR). It describes best practices for notified bodies in performing conformity assessment procedures relating to the verification of manufactured class D IVDs.

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We would like to say thank you for your loyalty and wish you a Merry Christmas and Happy New Year!

Your Regulatory Globe Team

REGULATORY GLOBE

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