PROMEPLA

PRESS RELEASE
Monaco, February 3rd 2025

Promepla S.A.M obtains CE marking under MDR (EU) 2017/745 by notified body IMQ S.p.A for nearly 90 medical device references.

Promepla S.A.M. has received its CE marking certificate for almost 90 of its products under Regulation (EU) 2017/745 on medical devices (MDR). The certificate, issued by the Italian notified body IMQ S.p.A (0051), covers class Is (sterile) and class lla devices, divided into 5 families: ophthalmology, dental, infusion, general surgery and general surgery smoke evacuation. Promepla S.A.M. also markets MDR self-certified class I medical devices.

This CE mark confirms Promepla's position as a leading player in the field of medical devices.

Michel Sasportes, CEO of Promepla, comments: *'Obtaining this CE mark is the fruit of a long and hard effort by our teams, in collaboration with our customers and partners. We are proud of this collective success, which is proof of our dynamism and our ability to adapt to regulatory changes.'*

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As a reminder, medical devices (MD) cannot be released in Europe without CE marking.
All MD manufacturers must implement a quality management system within their organisation. In July 2024, Promepla S.A.M. renewed its ISO 13485 certificate, a guarantee of compliance and continuous improvement.

In order to affix the CE mark, an MD manufacturer must also compile technical documentation (TD) that meets the requirements of European regulations (MDR) and demonstrates the safety and performance of its products. Depending on the risk class of the device, a notified body, designated in accordance with the Regulation, assesses the TD with a view to issuing the CE marking certificate, proof of the product's conformity.

Kim Herbert, new Quality & Regulatory Affairs Director of Promepla, comments: *'On the strength of our experience in Europe and around the world, our services include assisting our customers with the certification process for Regulation (EU) 2017/745, as well as providing support for the registration of medical devices outside the European Union.'*

About Promepla

Promepla S.A.M. is a designer, contract manufacturer and distributor of single-use components and assemblies for medical devices and biopharmaceutical solutions. Headquartered in Monaco, the Promepla group employs nearly 450 people and has 5 production and assembly sites in France (Signes, Le Bousquet d'Orb), Germany (Cadolzburg), Morocco (Casablanca) and Tunisia (Tunis), with 3,500 m^2 of ISO 8 clean rooms. From design to manufacture, packaging, sterilisation and regulatory support, Promepla S.A.M. offers "all-in-one" services tailored to each of its customers. A fast-growing group, Promepla acquired in 2022 the German company A. Hopf, specialising in plastic injection, and Medical Tubing, a French company specialising in extrusion, in 2023.
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