

EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapters I and III

Registration No.: HZ 2460489-1
Manufacturer: ISOMED SARL
ZAE les Pointes
230 rue des Grands Prés
60230 Chambly
France

EUDAMED Single
Registration No.: FR-MF-000018485

Products:

Products of class III:

C01020401 – Central I.V. Catheters,
Subcutaneous implantable venous access port
systems, single chamber.

Authorized representative(s): Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2026-10-06

The Notified Body hereby declares that the requirements of Annex IX, Chapter I of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 73083199-100
Effective date: 2026-10-06
Expiry date: 2031-10-05
Issue date: 2026-10-06


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This certificate can be validated on <https://www.certipedia.com>

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