EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter II

Registration No.:	IZ 2460489-1
Manufacturer:	ISOMED SARL ZAE les Pointes 230 rue des Grands Prés 60230 Chambly France
EUDAMED Single Registration No.:	FR-MF-000018485
General product group name:	C01020401 – Subcutaneous implantable venous access port systems, single chamber MDN 1101 Non-active cardiovascular, vascular and neurovascular implants
Basic UDI-DI:	37004845INFUKTJM
Classification:	III
Product name:	INFU-KT implantable Access Port kit
Models and types:	IVM: INFU-KT Micro venous access port kit IVT: INFU-KT Standard venous access port kit IVP: INFU-KT Low profile venous access port kit IVB: INFU-KT Optimized standard venous access port kit IVS: INFU-KT Optimized low profile venous access port kit
Intended use:	The INFU-KT access ports are intended to provide repeated access to the central vascular system for the delivery of

The Notified Body hereby declares that the requirements of Annex IX, Chapter II of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate is required before placing the listed products on the market.

Report No.:	73083199-240
Effective date:	2026-10-06
Expiry date:	2031-10-05
Issue date:	2026-10-06

Dominika Książek
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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	medications, intravenous fluids, parenteral nutrition, and sampling of blood.
Authorized representative(s):	Not Applicable

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

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