Pentaferte Italia Srl unipersonale

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EU Declaration of conformity (DoC)

The company listed below,

SRN:	IT-MF-000040982
Business name:	PENTAFERTE ITALIA s.r.l.
Adress:	Viale Piane Nocella, 23- 64012 CAMPLI (TE)- ITALY
Tel. Nr.:	+39 0861 560201
E-Mail:	info@numantec.eu

declares that this EU Declaration of Conformity is issued under own sole responsibility and it's referred to the following medical devices, of which PENTAFERTE ITALIA s.r.l. is the legal manufacturer:

REF.	DESCRIPTION	TRADEMARK	#
060022424	3 ml prefilled syringe, 0,9% NaCl	PENTAFLUSH	SPS
060022524	5 ml prefilled syringe, 0,9% NaCl	PENTAFLUSH	SPS
060022624	10 ml prefilled syringe, 0,9% NaCl	PENTAFLUSH	SPS
060022725	20 ml prefilled syringe, 0,9% NaCl	PENTAFLUSH	SPS

Intended use: PENTAFLUSH prefilled saline syringe is exclusively intended for the in-situ flushing of vascular access devices

For this purpose, it also declares that the aforementioned devices:

- are identified with the BASIC UDI-DI nr: **801526210854**
- belong to Class IIb, according to the rule 3 (Annex VIII of the MDR 745/2017)
- are in conformity with the following relevant Union legislation:
  - Regulation nr. 745/2017 on Medical Devices
  - Regulation (CE) nr. 1907/2006 (REACH)
- are designed, manufactured and controlled according to the applicable harmonized standards and the Common Specification listed in the relevant Technical Documentation
- will be sold with CE0051 mark as per the certificate n° 048/MDR issued by Notified Body IMQ, Via Quintiliano 43, 20138 Milano-ITALY, according to Annex IX chapters I and III of the MDR 2017/745.

Campli, 13/04/2026

Signed on behalf of Gabriele Giovanelli (Legal Representative)

Rosa Di Gioia (Quality & Regulatory Manager)