www.pentaferte.com
info@pentaferte.com

EU Declaration of conformity (DoC)

The company listed below,

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

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
002022120	Syringe 1 ml LUER 100-UI	PENTA
002022140	Syringe 1 ml TUB.	PENTA
002022140F	Syringe 1 ml TUB. F	PENTA
002022142	Syringe 1 ml TUB. LUER LOCK	PENTA
002022300	Syringe 2,5 ml	PENTA
002022420	Syringe 3 ml LUER LOCK	PENTA
002022500	Syringe 5 ml	PENTA
002022610	Syringe 10 ml ECC	PENTA
002022710	Syringe 20 ml ECC	PENTA
002022960	Syringe 60 ml ECC	PENTA
002022980	Syringe 60 ml CAT	PENTA
002022C30	Syringe 100 ml CAT	PENTA

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

- are identified with the **UDI-DI BASIC** nr. **80152621014N**
- belong to Classe 1SM, according to the rule 2 (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 745/2017.

Campli, 28/09/2022

Signed on behalf of Gianluca Romagnoli (Chairman/Legal Representative)

Rosa Di Gioia (Quality & Regulatory Manager/ PRRC)