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
00202212H58	Syringe 1 ml 100-UI with needle 25Gx5/8"	PENTA
00202214H58	Syringe 1 ml TUB with needle 25Gx5/8"	PENTA
00202214H58F	Syringe 1 ml TUB with needle 25Gx5/8"	PENTA
00202214I05	Syringe 1 ml TUB with needle 26Gx1/2"	PENTA

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

- are identified with the **UDI-DI BASIC** nr. **80152621034S**
- belong to Classe IIA, 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