

EU Declaration of conformity (DoC)

The company listed below,

Business name:	PENTAFERTE ITALIA s.r.l.
Address:	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
002612620	Syringe 10ml CRN without needle for CRONO infusion pumps	CRONO
00261262B12	Syringe 10ml CRN with needle 19Gx11/2" for CRONO infusion pumps	CRONO
002612720	Syringe 20ml CRN without needle for CRONO infusion pumps	CRONO
00261272B12	Syringe 20ml CRN with needle 19Gx11/2" for CRONO infusion pumps	CRONO
00261272B12PS	Syringe 20ml CRN with needle 19Gx11/2" for CRONO infusion pumps	CRONO PS
00261282B12	Syringe 30ml CRN with needle 19Gx11/2" for CRONO infusion pumps	CRONO
00261282B12I	Syringe 25,5ml CRN with needle 19Gx11/2" for CRONO infusion pumps	INFONDE
002612920	Syringe 50ml CRN without needle for CRONO infusion pumps	CRONO
002612C20	Syringe 100ml CRN without needle for CRONO infusion pumps	CRONO

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

- are identified with the **UDI-DI BASIC nr. 80152621024Q**
- 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)
- the applicable harmonized standards and the Common Specification for the design, production and control of the devices are 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.

Campoli, 27/09/2022

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


Rosa Di Gioia (Quality & Regulatory Manager/ PRRC)