CANÈ S.p.A. - Socio Unico
Direzione e coordinamento CMF s.r.l.
Cap. Soc. Euro 1.000.000,00 i.v.
C.F. - P.IVA - Reg. Impr. TO: 04384410017
R.E.A. TO N. 629783
Reg. A.E.E.: IT08020000002254
EORI IT04384410017
REX ITREXIT04384410017

REG. N. 3506
ISO 9001:2015
ISO 13485:2016

EU DECLARATION OF CONFORMITY

CANÈ S.p.A.
SRN n° IT-MF-000013520
via Cuorgné 42/a - 10098 Rivoli (TO) - Italy

hereby declares, under its sole responsibility, that the following products:

BASIC UDI-DI (GMN)	INTENDED PURPOSE	MODEL	REF	UDI-DI (GTIN)
805061661-PS-PID-82	Ambulatory pumps for subcutaneous infusions of immunoglobulins	CRONO S-PID 100	PS3AF	08050616613028
		CRONO S-PID 30	PS3TL	08050616613080
		CRONO S-PID 50	PS3PL	08050616613004
		CRONO S-PID4 100	PS4AK	08050616614063
		CRONO S-PID4 50	PS4AQ	08050616614148
		CRONO SUPER PID	PS3LL	08050616613066
		CRONO TWIN	PS3KL	08050616613202

- are **class IIb** medical devices, according to Rule 12 of Annex VIII of European regulation 2017/745 and subsequent changes;
- comply with the **general safety and performance requirements** of Annex I of European regulation 2017/745 and subsequent changes, as stated by MDR 00002-A and MDR 00002-B certificates, issued by notified body n° 0476 - KIWA Cermet Italia S.p.A., via Cadriano 23, I-40057 Granarolo dell'Emilia (BO);
- have been designed according to the following **main product technical standards**:
  - IEC 60601-1: 2005 AMD2:2020 - Medical electrical equipment. General requirements for basic safety and essential performance.
  - IEC 60601-1-2: 2014 AMD1:2020 - Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility. Requirements and tests.
  - IEC 60601-1-8: 2006 AMD2:2020 - Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

- IEC 60601-1-11: 2015 AMD1:2020 - Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-2-24: 2012 - Medical electrical equipment. Particular requirements for the basic safety and essential performance of infusion pumps and controllers.
- ISO 10993-1: 2018 - Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process.
- ISO 14971: 2019 - Medical devices. Application of risk management to medical devices.
- ISO 15223-1: 2021 - Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied.

The CANÈ S.p.A. **quality system** is certified by KIWA Cermet Italia S.p.A., via Cadriano 23, I-40057 Granarolo dell'Emilia (BO), according to the following standards:

- ISO 9001 - Quality management systems - Requirements - as stated by certificate n° 3506-A;
- ISO 13485 - Medical devices - Quality management systems - Requirements for regulatory purposes - as stated by certificate n° 3506-M.

Rivoli (TO), 23.02.2023

CANÈ S.p.A.

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P. IVA/C.F. 04384410017

Claudio Canè
Managing Director
Person Responsible for Regulatory Compliance