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-PAR-84	Ambulatory pumps for subcutaneous infusions of apomorphine in the treatment of Parkinson's disease	CRONO APO-GO 50	PS3XL	08050616613301
		CRONO APO-GO III	PS3CL	08050616613325
		CRONO PAR	PS3DL	08050616613103
		CRONO PAR 30	PS3VL	08050616613127
		CRONO PAR 50	PS3FL	08050616613141
		CRONO PAR4 20	PS4AH	08050616614025
		CRONO PAR4 30	PS4AI	08050616614087
		CRONO PAR4 50	PS4AM	08050616614100

- 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.

CANE' S.p.A.
Via Cuorgnè n° 42/a
10098 RIVOLI (TO)
Tel. 011.9574872 - Fax 011.9598880
P. IVA/C.F. 04384410017

Claudio Canè
Managing Director
Person Responsible for Regulatory Compliance