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. hereby declares, under its sole responsibility, that

Portable Infusion Pumps
Serie III

- CRONO
- CRONO 30
- CRONO 50 SC
- CRONO APO-GO 50
- CRONO APO-GO III
- CRONO BASIC
- CRONO ND
- CRONO P
- CRONO PAR
- CRONO PAR 30
- CRONO PAR 50
- CRONO SC
- CRONO S-PID
- CRONO S-PID 100
- CRONO S-PID 30
- CRONO S-PID 50
- CRONO SUPER PID
- CRONO TWIN
- CRONO TWIN ND
- INFONDE

- are **class IIb** medical devices, according to Rule 11 - 2° paragraph of Annex IX of 93/42/EEC European directive and subsequent changes introduced by the 2007/47/EC European directive;
- comply with the **essential requirements** of Annex I of the 93/42/EEC European directive and subsequent changes introduced by the 2007/47/EC European directive, as stated by the N MED - 9813 certificate, 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 - Medical electrical equipment. General requirements for basic safety and essential performance.
  - IEC 60601-2-24 - Medical electrical equipment. Particular requirements for the basic safety and essential performance of infusion pumps and controllers.

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

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), 18.05.2021

CANÈ S.p.A.

Claudio Canè
Managing Director