

EU DECLARATION OF CONFORMITY

CANÈ S.p.A. hereby declares, under its sole responsibility, that

Portable Infusion Pumps Serie IV

- **CRONO PAR4 20**
 - **CRONO S-PID4 100**
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- 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.

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