

## EU DECLARATION OF CONFORMITY

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

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

BASIC UDI-DI (GMN)	INTENDED USE	MODEL	REF	UDI-DI (GTIN)
805061661CCSJT6G	Electric device used for the filling of crn® CRONO® Réservoir	CRONO JET 10/20	CCSJT2	08050616619402
		CRONO JET 50	CCSJT5	08050616619006
		CRONO JET 100	CCSJT1	08050616619105

- are **class I** medical devices, according to Rule 13 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.

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), 20.06.2022

CANÈ S.p.A.

**CANÈ' S.p.A.**  
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Claudio Canè

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Person Responsible for Regulatory Compliance