

# CERTIFICATE

**The Certification Body TÜV Rheinland Italia S.r.l.**

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

**Roncadelle Operations S.r.l.**

**Via Renolda, 10**

**IT - 25030 Castel Mella (BS)**

has established and applies a quality management system  
for the following scope:

**Design and development, manufacture and place on the market of sterile disposable  
needles and syringes for injection.**

Through an Audit, Report No. 7979684010MPI29, proof has been furnished that the  
quality management system fulfils the requirements of the standard

**UNI CEI EN ISO 13485:2021**

Please refer to the Quality Manual for the details about  
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0302203**

This Certificate is valid from 2025/08/02 to 2028/08/01

The reference date for all the next audits is (day-month): 28/04

**Milan, 2025/07/30.** First Certification: 2022/08/02



The certification responsible: Massimiliano Testi  
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of  
the Directives 93/42/EEC, 90/385/EEC, 98/79/EC or  
Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled



MS N° 0083

Membro degli Accordi di Mutuo  
Riconoscimento EA, IAF e ILAC.  
Signatory of EA, IAF and ILAC  
Mutual Recognition Agreements.



Management  
System  
EN ISO 13485:2016  
+AC:2018+A11:2021



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