

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000351065-MSC-ACCREDIA-ITA

Initial certification date:
18 May 2020

Valid:
18 May 2026 – 17 May 2029

This is to certify that the management system of
InnovHeart S.r.l.
Via Ribes, 5 - 10010 Colletterto Giacosa (TO) - Italy
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2016

This certificate is valid for the following scope:

Research and development of transcatheter atrio-ventricular valve prostheses and related accessories.
Research and development of delivery system for atrio-ventricular transcatheter valve prostheses

Place and date:
Vimercate (MB), 18 May 2026

For the issuing office:
DNV - Business Assurance
Via Energy Park, 14, - 20871 Vimercate (MB) - Italy



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Claudia Baroncini
Management Representative

Appendix to Certificate

InnovHeart S.r.l.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
InnovHeart S.r.l.	Via Ribes, 5 - 10010 Colleretto Giacosa (TO) - Italy	Research and development of transcatheter atrio-ventricular valve prostheses and related accessories
Innovheart U.S. Inc.	70 WELLS AVE. STE 203, Newton, Massachussets, MA, 02459, USA	Research and development of delivery system for atrio-ventricular transcatheter valve prostheses