

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
10000351065-MSC-ACCREDIA-ITA

Initial certification date:  
18 May 2020

Valid:  
18 May 2023 – 17 May 2026

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), 17 May 2023



SGQ N° 003 A  
SGA N° 003 D  
SGE N° 007 M  
SCR N° 004 F

EMAS N° 009 P  
PRD N° 003 B  
PRS N° 094 C  
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento  
SGQ, SGA, PRD, PRS, ISP, GIG, LAB e LAT, di MLA IAF  
per gli schemi di accreditamento SGQ, SGA, SSI, FSM  
e PRD e di MRA ILAC per gli schemi di accreditamento  
LAB, MED, LAT e ISP

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



**Claudia Baroncini**  
Management Representative



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## 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 Colletterto Giacosa (TO) - Italy	Research and development of transcatheter atrio-ventricular valve prostheses and related accessories
Innovheart U.S. Inc	55 Chapel Street Suite, Newton, Massachusetts, MA, 010, USA	Research and development of delivery system for atrio-ventricular transcatheter valve prostheses

