

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
10000351065-MSC-ACCREDIA-ITA

Initial certification date:  
18 May 2020

Valid:  
18 May 2020 – 17 May 2023

This is to certify that the management system of  
**InnovHeart S.r.l.**  
Via Ribes, 5 - 10010 Collettero 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, development and qualification of transcatheter atrio-ventricular valve prostheses and related accessories**

Place and date:  
Vimercate (MB), 13 October 2021



SGQ N° 003 A	EMAS N° 009 P
SGA N° 003 D	PRD N° 003 B
SGE N° 007 M	PRS N° 094 C
SCR N° 004 F	SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento SGQ, SGA, PRD, PRS, ISP, GHG, 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

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

