

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 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, development and qualification of transcatheter atrio-ventricular valve prostheses and related therapeutic devices

Place and date:
Vimercate (MB), 20 January 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 GL - Business Assurance
Via Energy Park, 14, - 20871 Vimercate
(MB) - Italy

Zeno Beltrami
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, development and qualification of transcatheter atrio-ventricular valve protheses and related therapeutic devices
Innovheart U.S. Inc	55 Chapel Street SuiteNewton, Massachusetts, MA, 010, USA	Design and development of sterile transcatheter mitral heart valve as Saturn delivery system