

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.I.

Via Ribes, 5 - 10010 Colleretto 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

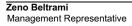
Place and date: Vimercate (MB), 13 October 2021



PRD Nº 003 B PRS Nº 094 C SSI Nº 002 G

N° 003 A N° 003 D N° 007 M N° 004 F

Membro di MA EA per gli schemi di accreditamento SGQ, SGA, PRD, PRS, ISP, GHG, LAB e LAT, di MLA IAI per gli schemi di accreditamento SGQ, SGA, SSI, FSM e PRD e di MRA LIAC 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





Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Business Assurance Italy S.r.I., Via Energy Park, 14 - 20871 Vimercate (MB) - Italy - TEL: +39 68 99 905. www.dnv.it



Appendix to Certificate

InnovHeart S.r.I.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
InnovHeart S.r.I.	Via Ribes, 5 - 10010 Colleretto Giacosa (TO) - Italy	Research, development and qualification of transcatheter atrio-ventricular valve protheses and related accessories
Innovheart U.S. Inc	55 Chapel Street SuiteNewton, Massachusetts, MA, 010, USA	Research, development and qualification of delivery system for atrio-ventricular transcatheter Saturn valve prostheses

