

# CERTIFICATE

Number: 2267648

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## HighLife SAS

100 avenue de Suffren  
75015 Paris  
France

including the implementation meets the requirements of the standard:

# EN ISO 13485:2016 ISO 13485:2016

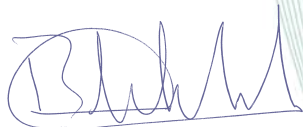
### Scope:

Design, development, manufacture and distribution of Prosthetic Implantable Heart Valves, Sub-annular Implants, Transseptal Delivery Catheters, Sub-annular Delivery Catheter Loop Placement Catheters, Crimper and Valve Loading Tool for the clinical application of mitral valve replacement.

Certificate expiry date: 1 August 2027  
Certificate effective date: 1 August 2024  
Certified since: 1 August 2024

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.M. McKenzie  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



# ADDENDUM

To certificate: 2267648

The management system of the organization(s) and/or location(s) of:

## HighLife SAS

100 avenue de Suffren  
75015 Paris  
France

Certified organization(s) and/or locations:

Location	Certification scope / Activity
Highlife Medical, Inc 12 Goodyear, Suite 125 92618 Irvine, CA United States Of America	Design, development and manufacture of Prosthetic Implantable Heart Valves, Sub-annular Implants, Transseptal Delivery Catheters, Sub-annular Delivery Catheter Loop Placement Catheters, Crimper and Valve Loading Tool for the clinical application of mitral valve replacement.

Addendum expiry date: 1 August 2027

Addendum effective date: 1 August 2024