

# CERTIFICATE

Number: 2100419

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

## Variass Medical Systems B.V.

Nipkowlaan 5  
9207 JA Drachten  
The Netherlands

including the implementation meets the requirements of the standard:

## EN ISO 13485:2016

Scope:

Contract manufacturing and distribution of:

- active medical device components
- organ perfusion systems for the area of organ transplantations
- blood and fluid warming systems, for the area of intravenous fluid therapies.

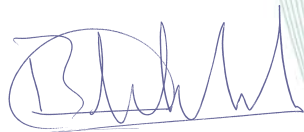
Certificate expiry date: 1 September 2026

Certificate effective date: 1 September 2023

Certified since: 12 September 2008

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: 2100419

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

## Variass Medical Systems B.V.

Nipkowlaan 5  
9207 JA Drachten  
The Netherlands

Certified organization(s) and/or locations:

Different scope

Variass Development B.V.  
Nipkowlaan 5  
9207 JA Drachten  
The Netherlands

Design and development of  
active medical device components, including electronics,  
mechanics and software.

Addendum expiry date: 1 September 2026

Addendum effective date: 1 September 2023