

# CERTIFICATE

Number: 2252058

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

## Artinis Medical Systems B.V.

Einsteinweg 17  
6662 PW Elst  
The Netherlands

including the implementation meets the requirements of the standard:

# EN ISO 13485:2016

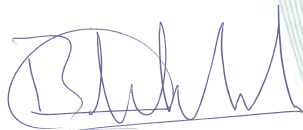
### Scope:

Design and development, manufacture and distribution of near-infrared spectroscopy devices (hardware and software) for monitoring of tissue oxygenation for clinical use.

Certificate expiry date: 1 July 2024  
Certificate effective date: 25 October 2022  
Certified since: 13 July 2021

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.A. McKenzie  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed





# ADDENDUM

To certificate: 2252058

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

## Artinis Medical Systems B.V.

Einsteinweg 17  
6662 PW Elst  
The Netherlands

Certified organization(s) and/or locations:

Different scope

Artinis Medical Systems B.V.  
Einsteinweg 15  
6662 PW Elst  
The Netherlands

Design and development, manufacture and distribution of near-infrared spectroscopy devices (hardware and software) for monitoring of tissue oxygenation for clinical use.

Addendum expiry date: 1 July 2024  
Addendum effective date: 25 October 2022