

CERTIFICATE

Number: 2148395

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

Itémedical B.V.

De Ooyen 5 a
4191 PB Geldermalsen
Netherlands

including the implementation meets the requirements of the standard:

ISO 13485:2016

Scope:

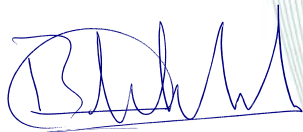
Design and development, production, distribution, installation and servicing of software for medical device data communication and alarm management.

Distribution, installation and servicing of third party acute and critical care products.

Certificate expiry date: 1 April 2027
Certificate effective date: 9 March 2026
Certified since: 1 April 2012

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



F. Godeke
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2148395

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

Itémedical B.V.

De Ooyen 5 a
4191 PB Geldermalsen
Netherlands

Certified organization(s) and/or locations:

Different scope

IteCardio B.V.
De Ooyen 5 a
4191 PB Geldermalsen
Netherlands

Distribution, installation and servicing of third party acute and critical care products

Addendum expiry date: 1 April 2027
Addendum effective date: 9 March 2026