

# CERTIFICATE

Number: 2168451

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

## Relitech B.V.

Van Siburgstraat 34  
3863 HW Nijkerk  
The Netherlands

including the implementation meets the requirements of the standard:

# ISO 13485:2016 EN ISO 13485:2016

### Scope:

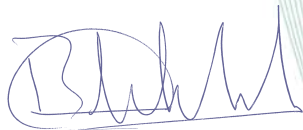
Design, development, manufacture, installation and servicing of:

- Therapeutic and diagnostic active medical device components
- Devices for whole body and intraperitoneal hyperthermia treatment
- Cold plasma devices for wound care
- In vitro diagnostic analyzers used in the near-patient/point-of-care detection and quantification of specific substances in biological samples such as blood, urine, or saliva

Certificate expiry date: 1 July 2026  
Certificate effective date: 1 July 2023  
Certified since: 4 July 2014

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: 2168451

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

## Relitech B.V.

Van Siburgstraat 34  
3863 HW Nijkerk  
The Netherlands

Certified organization(s) and/or locations:

Different scope

Relitech Systems B.V.  
Van Siburgstraat 34  
3863 HW Nijkerk  
The Netherlands

Manufacture, installation and servicing of:

- Therapeutic and diagnostic active medical device components
- Devices for whole body and intraperitoneal hyperthermia treatment
- Cold plasma devices for wound care
- In vitro diagnostic analyzers used in the near-patient/point-of-care detection and quantification of specific substances in biological samples such as blood, urine, or saliva

Relitech Development B.V.  
Van Siburgstraat 34  
3863 HW Nijkerk  
The Netherlands

Design and development, of:

- Therapeutic and diagnostic active medical device components
- Devices for whole body and intraperitoneal hyperthermia treatment
- Cold plasma devices for wound care
- In vitro diagnostic analyzers used in the near-patient/point-of-care detection and quantification of specific substances in biological samples such as blood, urine, or saliva

Addendum expiry date: 1 July 2026  
Addendum effective date: 1 July 2023