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

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra.nl Company registration 09085396

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