

CERTIFICATE

Number: 2218912

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

The Surgical Company International B.V.

doing business as The 37Company

Beeldschemweg 6F
3821 AH Amersfoort
The Netherlands

Manufacturer Facility Identifier F004448

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

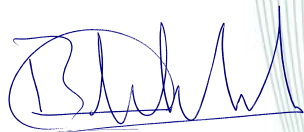
Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

Design, development, manufacturing, distribution and servicing of patient temperature management systems for the areas of anaesthesiology, orthopaedics and urology.

Certificate expiry date: 2026-01-01
Certificate effective date: 2023-02-15
Certified since: 2020-01-14

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

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: 2218912

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

The Surgical Company International B.V.

doing business as The 37Company

Beeldschermweg 6F

3821 AH Amersfoort

The Netherlands

Certified organization(s) and/or locations:

Different scope

The Surgical Company International BV

Bedrijvenpark Twente Noord 48

7602 KR Almelo

The Netherlands

Facility Identifier F005899

Manufacturing of non-sterile warming blankets, distribution of patient temperature management systems for the areas of anaesthesiology, orthopaedics and urology.

Addendum expiry date: 2026-01-01

Addendum effective date: 2023-02-15