

# CERTIFICATE

Number: 2245847

The management system of:

## Stihler Electronic GmbH

Gaussstrasse 4  
70771 Leinfelden-Echterdingen  
Germany

Manufacturer Facility Identifier F003766

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

Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009

Canada: Medical Devices Regulations - Part 1- SOR 98/282

United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

### Scope:

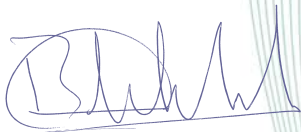
Design and development, production and distribution of diaphanoscopes for transillumination and devices for hypothermia and decubitus prevention

Certificate expiry date: 2023-04-01

Certificate effective date: 2021-09-06

Certified since: 2020-04-02

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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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.

