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. 665/2022, 551/2021 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, manufacture, distribution and service of diaphanascopes for transillumination and devices for maintaining normothermia and for decubitus prevention.

Certificate expiry date:	2026-04-01
Certificate effective date:	2025-04-10
Certified since:	2020-04-02

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Certification Manager

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https://www.dekra-checkme.com/org

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM