



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
7085GB451230224

Final assessment report no.  
7085AU12F

Effective date  
2023-02-24

Expiry date  
2025-04-26

This is to certify that the management system of  
**Pierenkemper GmbH**  
Am Geiersberg 6, 35630 Ehringshausen, Germany  
Facility ID: F006032

With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard  
**ISO 13485:2016 and the following country-specific requirements**

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 and 4  
Brazil: RDC ANVISA n. 665/2022; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009  
Canada: Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)  
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act (as applicable)  
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

This certificate is valid for the scope of activities and products/services indicated  
on the following pages.

Place and date  
Hamburg, 2023-02-24

For the issuing office  
DNV MEDCERT GmbH  
Pilatuspool 2, 20355 Hamburg, Germany

DNV MEDCERT is an MDSAP  
authorised auditing organisation

**Markus Bianchi**  
Director Certification Body

The certificate is only valid when provided entirely with all of  
its pages. To verify the validity of this certificate, contact  
info@medcert.de

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820114 EN Rev 5 2022.11.16

AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)  
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

## Activities and products/services covered by this certificate

Design and development, manufacturing, distribution, and servicing of

- Nerve and muscle stimulators
- Vaginal and rectal electrodes
- Laser therapy devices
- RF lesion generators
- Biofeedback therapy systems
- Magnetic field therapy devices
- Ultrasonic physiotherapy equipment
- Acupuncture needles
- Associated accessories and consumables

## Sites covered by this certificate

Pierenkemper GmbH, Am Geiersberg 6, 35630 Ehringshausen, Germany  
Facility ID: F006032

No activities and products; certificate holder address only

Pierenkemper GmbH, Dreieiche 7, 35630 Ehringshausen, Germany  
Facility ID: F006048

Purchasing, storage, distribution of

- Nerve and muscle stimulators
- Vaginal and rectal electrodes
- Laser therapy devices
- RF lesion generators
- Biofeedback therapy systems
- Magnetic field therapy devices
- Ultrasonic physiotherapy equipment
- Acupuncture needles
- Associated accessories and consumables

Pierenkemper GmbH, Wetzlarer Straße 41-43, 35630 Ehringshausen  
Facility ID: F006048

Design and development, manufacturing, distribution, installation, and servicing of

- Nerve and muscle stimulators
- Vaginal and rectal electrodes
- Laser therapy devices
- RF lesion generators
- Biofeedback therapy systems
- Magnetic field therapy devices
- Ultrasonic physiotherapy equipment
- Acupuncture needles
- Associated accessories and consumables

Pierenkemper GmbH, Philipp-Reis-Straße 5, 35321 Laubach, Germany  
Facility ID: F006210

Manufacturing and servicing of

- Nerve and muscle stimulators
- Vaginal and rectal electrodes
- Laser therapy devices
- RF lesion generators
- Biofeedback therapy systems
- Magnetic field therapy devices
- Ultrasonic physiotherapy equipment

Acupuncture needles Associated accessories and consumables