MEDCERT®
Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

Pierenkemper GmbH
Am Geiersberg 6
35630 Ehringshausen
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: **2019-12-17**
Expiry date: **2024-04-26**

Report No.: 7085FS08F
Process No.: QS – 7085
Certificate No.: 7085GB414191217

Hamburg, 2019-12-17

MEDCERT Certification Body
(Markus Bianchi

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

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Appendix of EC Certificate of Conformity

Process No.: QS – 7085
Certificate No.: 7085GB414191217

List of locations included in the scope of certificate

Dreieiche 7
35630 Ehringshausen
Germany

Wetzlarer Str. 41 – 43
35630 Ehringshausen
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
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Appendix of EC Certificate of Conformity

Process No.: QS – 7085
Certificate No.: 7085GB414191217

List of products / product categories included in the scope of certificate

- **Acupuncture needles**

– End of list –

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Pierenkemper GmbH

Am Geiersberg 6

35630 Ehringshausen

Germany

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: info@medcert.de

Date: 2022-12-01

Our reference: QS-7085

Confirmation letter correcting and complementing information on an existing certificate in accordance with Article 120 (3) of Regulation (EU) 2017/745

Directive and annex	**Directive 93/42/EEC, Annex V**
Organisation	**Pierenkemper GmbH**
Registered place of business	**Am Geiersberg 6 35630 Ehringshausen Germany**
Certificate number	**7085GB414191217**
Certificate expiry date	**2024-04-26**
Scope of certification	**Acupuncture needles**
Description of change(s)	**addition of a facility to the scope of certification**
Effective date of change(s)	**2022-12-01**

To whom it may concern,

DNV MEDCERT GmbH (previously: MEDCERT Prüfungs- und Zertifizierungsgesellschaft für die Medizin GmbH), a Notified Body according to Regulation (EU) 2017/745 on medical devices (MDR)[1] (NB 0482), herewith declares that, pursuant to Article 120 (1) of MDR, since 26 May 2021, no certificate under the Directive 93/42/EEC (Medical Device Directive, or MDD)[2] is allowed to be issued any more.

Consequently, pursuant to guidance MDCG 2020-3[3], this Confirmation Letter is valid together with and complements the above-referenced certificate. We as a Notified Body are continuing to perform the surveillance activities for MDD certificates issued by DNV MEDCERT which are still valid, as laid out in the Article 120 (3) of MDR.

We hereby confirm that the above-referenced certificate has been issued to the above-referenced manufacturer and is still valid with the change(s) described in this letter.

Hamburg, 2022-12-01

Markus Bi[illegible]chi
Director C[illegible]rtification Body

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (http://data.europa.eu/eli/reg/2017/745/2020-04-24).
[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (http://data.europa.eu/eli/dir/1993/42/2007-10-11).
[3] MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (available on https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en).