MED CERT®

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:

Pentracor GmbH
Neuendorfstraße 23 b/d
16761 Hennigsdorf
Germany

with locations listed in the appendix

has introduced 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 II without section 4

This certification is subject to surveillance by MEDCERT.

This certificate is valid until 27 August 2024

Report No.: 7220FS06F
Process No.: QS – 7220
Certificate No.: 7220GB410190829

Hamburg, 29 August 2019

MEDCERT Certification Body
(Dr. Andreas Schich)

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 – 7220
Certificate No.: 7220GB410190829

List of locations included in the scope of certificate

Pentracor GmbH
Hindenburgdamm 30
12203 Berlin
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 – 7220
Certificate No.: 7220GB410190829

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

Adsorber for therapeutic apheresis

– End of list –

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Pentracor GmbH
Neuendorferstraße 23 b/d
16761 Henningsdorf
Deutschland

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 II**
Organisation	**Pentracor GmbH**
Registered place of business	Neuendorferstraße 23 b/d 16761 Henningsdorf Deutschland
Certificate number	7220DE410190829 7220GB410190829…
Certificate expiry date	2024-05-27
Scope of certification	Adsorber for therapeutic apheresis
Description of change(s)	Addition of a facility to the scope of certification
Effective date of change(s)	2022-10-27

To whom it may concern,

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 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.

[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).

MEDCERT
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für die Medizin GmbH
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Handelsregister: Hamburg HRB 55912
Steuernummer 48/724/00449
Ust-Identnummer: DE164312394

Bankverbindung:
Deutsche Bank – Konto-Nr.: 27 780 90 - BLZ 200 700 00
IBAN: DE58200700000277809000 - BIC: DEUTDEHHXXX
Hamburger Sparkasse - Konto-Nr.: 1382 120 788 - BLZ 200 505 50
IBAN: DE13200505501382120788 - BIC: HASPDEHHXXX

We hereby confirm that the aforementioned change(s) is (are) not considered significant change(s) to the design and/or intended purpose as described in Article 120 (3) of MDR. The evaluation of documents related to the change(s) has been completed and approved.

Hamburg, 2022-10-27

Marcus Harder
Director Certification Body

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