

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV

Signatory to the Multilateral Agreements of EA, ILAC and IAF for Mutual Recognition

Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the testing laboratory

VDE Prüf- und Zertifizierungsinstitut GmbH
Merianstraße 28
63069 Offenbach, Germany

is competent under the terms of DIN EN ISO/IEC 17025:2018 to carry out tests in the following fields:

Field: Medical devices in compliance with the requirements according to Directives 93/42/EEC and 90/385/EEC on independence

Testing fields/test items: **Safety tests and testing on compatibility with electromagnetic disturbances (EMC) of active medical devices**

The accreditation certificate shall only apply in connection with the notice of accreditation of 13.07.2020 with the accreditation number D-PL-12061-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 31 pages.

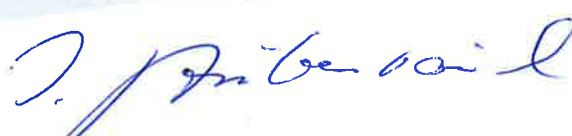
Registration number of the certificate: **D-PL-12061-01-02**

Frankfurt am Main,
13.07.2020

Dipl.-Ing. (FH) Ralf Egnér
Head of Division

Translation issued:
01.10.2020

Head of Division


The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
<https://www.dakks.de/en/content/accredited-bodies-dakks>

This document is a translation. The definitive version is the original German accreditation certificate.
See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

Office Berlin
Spittelmarkt 10
10117 Berlin

Office Frankfurt am Main
Europa-Allee 52
60327 Frankfurt am Main

Office Braunschweig
Bundesallee 100
38116 Braunschweig

The publication of extracts of the accreditation certificate is subject to the prior written approval by Deutsche Akkreditierungsstelle GmbH (DAkKS). Exempted is the unchanged form of separate disseminations of the cover sheet by the conformity assessment body mentioned overleaf.

No impression shall be made that the accreditation also extends to fields beyond the scope of accreditation attested by DAkKS.

The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) of 31 July 2009 (Federal Law Gazette I p. 2625) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (Official Journal of the European Union L 218 of 9 July 2008, p. 30). DAkKS is a signatory to the Multilateral Agreements for Mutual Recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). The signatories to these agreements recognise each other's accreditations.

The up-to-date state of membership can be retrieved from the following websites:

EA: www.european-accreditation.org

ILAC: www.ilac.org

IAF: www.iaf.nu