

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV
Signatory to the Multilateral Agreements of

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

Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the testing laboratory

Berlin Cert - Prüf- und Zertifizierstelle für Medizinprodukte GmbH an der Technischen Universität Berlin Dovestraße 6, 10587 Berlin

is competent under the terms of DIN EN ISO/IEC 17025:2005 and the Directives 93/42/EG and 90/385/EWG to carry out tests in the following fields:

Medical devices

Test fields/-products:

Physical mechanical and comparing tests of orthopedic and rehabilitation devices

Physical tests (mechanical and mechanical-electrical tests) for:

Active surgical devices, active dental devices, active endoscopic devices, monitoring devices, devices for radiation therapy and thermo therapy, devices for extra-corporal circulation, active ophthalmologic devices, active devices for patient positioning and transport, active devices for disinfection and sterilisation, active rehabilitation devices and software.

The accreditation certificate shall only apply in connection with the notice of accreditation of 2013-06-06 with the accreditation number D-PL-17591-01 and is valid until 2018-06-05. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 12 pages.

Registration number of the certificate: D-PL-17591-01-01

Frankfurt am Main, 2013-06-06

Dip.-Ing.(FH) Ralf Egner

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

Deutsche Akkreditierungsstelle GmbH

Office Berlin Spittelmarkt 10 10117 Berlin Office Frankfurt am Main Gartenstraße 6 60594 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