

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-17591-01-01 according to DIN EN ISO/IEC 17025:2005 and Directive 93/42/EWG und 90/385/EWG

Period of validity: 2013-06-06 to 2018-06-05

Date of issue: 2013-09-02

Holder of certificate:

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

Tests in the fields:

Field: Medical Devices (non active)

Testing field/ - products: Physical mechanical and comparing tests of orthopedic
and rehabilitation devices

Test Field	Testing product Product category	Test mode Test	Standard Test procedure
Physical mechanical and comparing tests	Orthopaedic and rehabilitation devices - Manually propelled wheelchairs, transit wheelchairs, push wheelchairs, shower and toilet wheelchairs	Test of the constructive characteristics, performance requirements - Static and dynamic stability, test of brakes	DIN EN 12183 ISO 7176-1 ISO 7176-3 ISO 7176-5 ISO 7176-7 ISO 7176-8 ISO 7176-15 Further applicable: DIN EN 12182

Test Field	Testing product Product category	Test mode Test	Standard Test procedure
Physical mechanical and comparing tests	Orthopaedic and rehabilitation devices - Manually propelled wheelchairs - Transit wheelchairs - Push wheelchairs, - Shower and toilet wheelchairs - Shower and toilet chairs, raised toilet seats - Walking frames - Rollators - Delta walking aids	Test of the constructive characteristics, performance requirements - Test of documentation and labeling information disclosed (provided by manufacture - Safety tests - Test of static stability, impact and fatigue resistance - Fatigue tests, strain test, test of labeling - Fatigue test, test of static strain, test of labeling	DIN EN 12183 DIN EN 1041 PA 021 <i>Further applicable:</i> DIN EN 12182 ISO 7176-8 DIN EN ISO 11199-1 DIN EN ISO 11199-2

Test Field	Testing product Product category	Test mode Test	Standard Test procedure
	<ul style="list-style-type: none"> - Walking tables - Elbow crutches - Parts for lower-limb prostheses 	<ul style="list-style-type: none"> - Fatigue test, test of static strain, test of labelling - Test of static, impact and fatigue strengths, Fall test - Static and dynamic strength test 	<p>DIN EN ISO 11199-3</p> <p>DIN EN ISO 11334-1 DIN EN ISO 11334-4</p> <p>DIN EN ISO 10328</p>
Physical mechanical and comparing tests	<p>Orthopaedic and rehabilitation devices</p> <ul style="list-style-type: none"> - Urethral catheters - Urine collection bags 	<p>Test of the constructive characteristics,</p> <ul style="list-style-type: none"> - solidity, balloon safety, Ballonsicherheit, folding stability - watertightness, solidity of suspension system, approach velocity 	<p>DIN EN 1616 DIN EN 1618 DIN EN 13868</p> <p>DIN EN ISO 8669-2</p>

Standards⁴:

DIN EN 1041:2008-11	Information supplied by the manufacturer of medical devices
DIN EN 1616:1999-05	Sterile urethral catheters for single use
DIN EN 1618:1997-04	Catheters other than intravascular catheters - Test methods for common properties

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ISO 7176-1:1999-10	Wheelchairs - Part 1: Determination of static stability
ISO 7176-3:2003-04	Wheelchairs - Part 3: Determination of effectiveness of brakes
ISO 7176-5:2008-06	Wheelchairs. Determination of dimensions, mass and maneuvering space
ISO 7176-7:1998-05	Wheelchairs - Part 7: Measurement of seating and wheel dimensions
ISO 7176-8:1998-07	Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
ISO 7176-15:1996-11	Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
DIN EN ISO 8669-2 1997-04	Urine collection bags - Part 2: Requirements and test methods
DIN EN ISO 10328:2007-04	Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods
DIN EN ISO 11199-1:2000-09	Walking aids manipulated by both arms - Requirements and test methods - Part 1: Walking frames
DIN EN ISO 11199-2:2005-07	Walking aids manipulated by both arms - Requirements and test methods - Part 2: Rollators
DIN EN ISO 11199-3:2005-07	Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables
DIN EN ISO 11334-1:2007-04	Assistive products for walking manipulated by one arm - Requirements and test methods - Part 1: Elbow crutches
DIN EN ISO 11334-4:1999-12	Walking aids manipulated by one arm – Requirements and test methods - Part 4: Walking sticks with three or more legs
DIN EN 12182:2012-07	Assistive products for persons with disability - General requirements and test methods
DIN EN 12183:2009-12	Manual wheelchairs - Requirements and test methods; German version EN 12183:2009
DIN EN 13868:2002-11	Catheters - Test methods for kinking of single lumen catheters and medical tubing

PA021:2007

Shower and toilet stool, toilet seat – safety tests

Approved Signatory

Name	Test field
Mr. Dr. Peter Diesing	All test fields
Mr. Frank Aßmann	All test fields
Mr. Thomas Born	All test fields
Mr. Salar Fallah	All test fields
Mr. Sven Lange	All test fields

Field: Medical devices (active)

Test field/ - products: Physical tests (mechanical and medical-electrical testing) 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.

Test field	Testing product Product category	Test mode Test	Standard Test procedure
Physical testing (mechanical and medical-electrical testing)	Active surgical devices and surgical assistive devices	Test for verification of conformity	DIN EN 60601-1 IEC 60601-1 VDE 0750-1
	Endoscopic devices	Safety	IEC 60601-2-18 DIN EN 60601-2-18 VDE 0750-2-18
	Active dental devices	Test for verification of conformity - Safety - Performance	DIN EN 60601-1 IEC 60601-1 VDE 0750-1 IEC 80601-2-60
	Monitoring devices of non-vital physiological parameters - Electroencepha- lographs	Test for verification of conformity - Safety - Performance	DIN EN 60601-1 IEC 60601-1 VDE 0750-1 DIN IEC 60601-2-26 VDE 0750-2-26

Test field	Testing product Product category	Test mode Test	Standard Test procedure
Physical testing (mechanical and medical-electrical testing)	- Physiological closed cycles	- Safety - Performance Test of requirements	IEC 60601-2-10 DIN EN 60601-2-10 VDE 0750-2-10
	Monitoring devices of vital physiological parameters - ambulant electrocardiograph ic systems - electrocardiograph s - Electrocardiograph ic monitoring devices	Test for verification of conformity - Safety - Performance - Safety - Performance - Safety - Performance	DIN EN 60601-1 IEC 60601-1 VDE 0750-1 DIN IEC 60601-2-47 VDE 0750-2-47 DIN IEC 60601-2-25 VDE 0750-2-25 DIN IEC 60601-2-27 VDE 0750-2-27

Test field	Testing product Product category	Test mode Test	Standard Test procedure
Physical tests (mechanical and medical-electrical testing)	devices for radiation therapy and thermotherapy - blankets, matts, mattresses for warming of patients for medical application	Test for verification of conformity - Safety - Performance	DIN EN 60601-1 IEC-60601-1 VDE 0750 DIN EN 60601-2-35 VDE 0750-35 DIN EN 80601-2-35
	- Devices with non- ionizing radiation <ul style="list-style-type: none"> • HF-surgical accessory • HF-surgical device • Ultrasonic medical diagnostic and monitoring equipment 	Test for verification of conformity - Safety - Performance - Safety - Performance	IEC 60601-2-2 DIN EN 60601-2-2 VDE 0750-2-2 IEC 6060-2-37 DIN EN 60601-2-37 VDE 0750-2-37
	Devices for extra- corporal circulation, infusion and haemopheresis - infusion pumps - infusion controller	Test for verification of conformity - safety	DIN EN 60601-1 IEC 60601-1 VDE 0750-1 IEC 60601-2-24 DIN EN 60601-2-24 VDE 0750-2-24
	Active ophthalmologic devices - devices for rem- oval of vitreous body - devices for rem- oval of lenses	Test for verification of conformity - Safety - Performance	DIN EN 60601-1 IEC 60601-1 VDE 0750-1 IEC 80601-2-58 DIN EN 80601-2-58 VDE 0750-2-58

Test field	Testing product Product category	Test mode Test	Standard Test procedure
Physical testing (mechanical and medical-electrical testing)	Active devices for patient positioning and transport	Test for verification of conformity	DIN EN 60601-1 IEC 60601-1 VDE 0750-1
	- Beds for medical purposes	- Safety - Performance	IEC 60601-2-52 DIN EN 60601-2-52 VDE 0750-2-52
	- Electrical beds for hospitals	- Safety - Performance	DIN EN 60601-2-38 VDE 0750-2-38
	Cleaning and desinfection devices	Tests of conformity of general and special specification for the safety of essential requirements	DIN EN ISO 15883-2 DIN EN ISO 15883-3
	Active rehabilitation devices	Test for verification of conformity	
	- Wheelchairs and scooter	- Safety - Performance	DIN EN 12184 ISO 7176-14
	Software	Test for verification of conformity	DIN EN 60601-1 IEC 60601-1 VDE 0750-1
	- Programmable, electrical, medical Systems	- Safety	IEC 60601-1-4 DIN EN 60601-1-4 VDE 0750-1-4

Standards

ISO 7176-14 : 2008-02

Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters

DIN EN 12184 : 2009-12

Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods (EN 12184:2009-07-07)

DIN EN ISO 15883-2 : 2009-12	Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006); German version EN ISO 15883-2:2009
DIN EN ISO 15883-3 : 2009-12	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006); German version EN ISO 15883-3:2009
DIN EN 60601-1 : 2007-07	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005); German version EN 60601-1:2006
DIN EN 60601-1 : 1996-03	Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988 + A1:1991 + A2:1995); German version EN 60601-1:1990 + A1:1993 + A2:1995
DIN EN 60601-1-4 : 2001-04	Medical electrical equipment - Part 1-4: General requirements for safety; Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1996 + A1:1999); German version EN 60601-1-4:1996 + A1:1999
DIN EN 60601-2-2 : 2010-01	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2009); German version EN 60601-2-2:2009
DIN EN 60601-2-10 : 2003-04	Medical electrical equipment - Part 2-10: Particular requirements for basic safety and essential performance of nerve and muscle stimulators (IEC 62D/810/CD:2009)
DIN EN 60601-2-18 : 2001-12	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment (IEC 60601-2-18:1996 + A1:2000); German version EN 60601-2-18:1996 + A1:2000

DIN EN 60601-2-24 : 1999-02	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998); German version EN 60601-2-24:1998
DIN EN 60601-2-25 : 2001-04	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25:1993 + A1:1999); German version EN 60601-2-25:1995 + A1:1999
DIN EN 60601-2-26 : 2004-01	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs (IEC 60601-2-26:2002); German version EN 60601-2-26:2003
DIN EN 60601-2-27 : 2006-08	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment (IEC 60601-2-27:2005); German version EN 60601-2-27:2006
DIN EN 60601-2-35 : 1997-12	Medical electrical equipment Part - 2-35: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use (IEC 60601-2-35:1996); German Version EN 60601-2-35:1996
DIN EN 60601-2-37 : 2012-05	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007); German version EN 60601-2-37:2008 + A11:2011
DIN EN 60601-2-38 : 2001-07	Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds (IEC 60601-2-38:1996 + A1:1999); German version EN 60601-2-38:1996 + A1:2000)
DIN EN 60601-2-47 : 2002-11	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems (IEC 60601-2-47:2001); German version EN 60601-2-47:2001

DIN EN 60601-2-49 : 2002-12	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
DIN EN 60601-2-52 : 2010-12	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009); German version EN 60601-2-52:2010
DIN EN 80601-2-58 : 2009-10	Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery (IEC 80601-2-58:2008); German version EN 80601-2-58:2009
IEC 80601-2-60 : 2012-02	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment

Approved Signatory

Name	Test field
Mr. Frank Aßmann	Active rehabilitation devices
Mr. Thomas Born	All test fields
Mr. Dr. Peter Diesing	All test fields
Mr. Salar Fallah	All test fields
Mr. Matthäus Fiedler	Active rehabilitation devices

Abbreviations

DIN	Deutsches Institut für Normung
EN	Europäische Norm
IEC	International Electrical Committee
ISO	International Organization for Standardization
Active medical devices	Medical electrical equipment, medical electrical systems and components
VDE	Vorschriftenwerk Verband der Elektrotechnik Elektronik Informationstechnik e.V.