Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-11321-12-01 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **04.03.2020**

Date of issue: 10.11.2020

Holder of certificate:

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München

at the location:

TÜV SÜD Product Service GmbH
Masurenweg 1-3, 30163 Hannover

Field:	Medical products under fulfillment of the requirements according to guidelines 93/42/EEC[2] and 90/385/EEC[3] at the independence
Testing fields/test items:	Safety tests of active medical devices and physical tests of non-active medical devices

The management system requirements in DIN EN ISO/IEC 17025 are written in language relevant to operations of testing laboratories and operate generally in accordance with the principles of DIN EN ISO 9001.

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

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Safety Tests	Active Medical Devices	Test for conformity	DIN EN 60601-1 IEC 60601-1
		Components and ME systems	
Safety Tests		Electrical tests and protection against electrical hazards	
		Mechanical strength and protection against mechanical hazards	
		Protection against excessive temperatures incl. fire prevention	
		Environmental simulation tests	
	Information presented by the manufacturer		
	- for components and assemblies		
	- for biocompatibility		
	- instructions / accompanying documents		
	- usability file		
	- for programmable electrical medical systems (PEMS)		
	- risk management file		
	- for radiation, ionizing / non-ionizing		
Physical tests	Non-Active Orthopaedic Devices and Rehabilitation Devices	Test for verification of conformity	

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
	- Walking aids		DIN EN 1985
	- Manual wheelchairs		DIN EN 12183
	- Technical aids for disabled persons	Materials	DIN EN 12182
		Sound and vibrations	
		Protection against excessive temperatures	
		Mechanical strength and protection against mechanical hazards	
		Cleaning and disinfection	
			Also applicable: ISO 7176-1 ISO 7176-3 ISO 7176-5 ISO 7176-7 ISO 7176-8 ISO 7176-15 ISO 7176-16 ISO 11199-1 ISO 11199-2 ISO 11199-3 ISO 11334-4 DIN EN 1021-2
Safety tests	Active Rehabilitation Devices and Protheses:	Test for verification of conformity	
	- Electrical wheelchairs and scooters and their chargers - Stair climbing devices	Performance Requirements	DIN EN 12184 ISO 7176-4 ISO 7176-6 ISO 7176-10
		Requirements for battery chargers Testing for verification of conformity	ISO 7176-28

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
	- Hearing aids	Verification of compliance with the general and specific requirements	IEC 60601-2-66
	- Technical aids for disabled persons	Materials	DIN EN 12182
		Sound and vibrations	
		Electrical tests and protection against electrical hazards	
Safety tests		Protection against excessive temperatures	
		Mechanical strength and protection against mechanical hazards	
		Cleaning and disinfection	
			Also applicable: ISO 7176-1 ISO 7176-2 ISO 7176-3 ISO 7176-5 ISO 7176-7 ISO 7176-8 ISO 7176-9 ISO 7176-14 ISO 7176-15 ISO 7176-16 DIN EN 1021-2 DIN EN 60529
Safety tests	Devices for Patient Positioning and Transport	Test for verification of conformity	

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
	- Aids for personal hygiene	Clinical evaluation / test	ISO 17966
		Materials Without inflammability test acc. to IEC 60695-11-10	
		Sound and vibrations	
		Electrical tests and protection against electrical hazards	
		Mechanical hazards	
		Mobile APPHs	
	- Lifters	General requirements for lifters	DIN EN ISO 10535
Safety tests		Special requirements for mobile lifters	
		Special requirements for stand and/or raising lifters	
		Special requirements for stationary lifters	
		Special requirements for flexible body support systems	
		Special requirements for rigid body support systems	
		Special requirements for bathtub lifters	
	- Medical beds - OP tables	Verification of compliance with the general and specific requirements	DIN EN 60601-2-52 IEC 60601-2-52 Also applicable: DIN EN 1021-2 DIN EN 60529 IEC 60601-2-46

If applicable, existing exclusions from partial tests of a test are not listed in the scope of the accreditation and must be communicated to the client by the laboratory when performing the contract review.

The accreditation assessment took place by taking the normative references of the European regulations (DIN EN) into account. The normative references of the international regulations (IEC, ISO) have not been taken into account, unless the referenced international revision versions of the standards are explicitly shown in the annex to the notification.

Standards[4]

DIN EN 1021-2 : 2014-08	Furniture - Assessment of the flammability of upholstered furniture - Part 2: A gas flame comparable to a match as an ignition source; German version EN 1021-2: 2014 DIN EN 1021-2: 2006-04⊗
DIN EN 1985 : 1999-02	Walking aids - General requirements and test methods; German version EN 1985:1998
DIN EN ISO 10535 : 2007-04	Hoists for the transfer of disabled persons - Requirements and test methods (ISO 10535:2006); German version EN ISO 10535:2006
DIN EN 12182 : 2012-07	Assistive products for persons with disability - General requirements and test methods; German version EN 12183:2012
DIN EN 12183 : 2014-06	Manual wheelchairs - Requirements and test methods; German version EN 12183:2014 DIN EN 12183: 2009-12⊗ Manual wheelchairs - Requirements and test methods; German version EN 12183:2009
DIN EN 12184 : 2014-06	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods; German version EN 12184:2014 EN 12184:2009⊗
DIN EN 60529 : 2014-09	Degrees of protection provided by the housing (IP code) (IEC 60529: 1989 + A1: 1999 + A2: 2013); German version EN 60529: 1991 + A1: 2000 + A2: 2013
DIN EN 60601-1 : 2013-12	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012); German version EN 60601-1:2006 + Cor. :2010 + A1:2013

	VDE 0750-1:2013-12 DIN EN 60601-1 : 2002-09⊗ - Medical electrical equipment - Part 1: General requirements for basic safety (IEC 60601-1 : 1988 +A1 : 1991 +A2 : 1995); German version EN 60601-1 : 1990 + A1 : 1993 + A2 : 1995 VDE 0750-1:2002-08⊗
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 VDE 0750-2-52:2010-12
IEC 60529 : 1989-11	Degrees of protection provided by enclosures (IP code) + Amendment 1 : 1999-11 + Amendment 2 : 2013-08
IEC 60601-1 : 2005-12	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance + Corrigendum 1 : 2006-12 + Corrigendum 2 : 2007-12 + Amendment 1 : 2012-07 IEC 60601-1 : 1988⊗ - Medical electrical equipment; part 1: general requirements for safety + Amendment 1 : 1991-11 + Amendment 2 : 1995-03
IEC 60601-2-46 : 2016-08	Medical Electrical Equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables
IEC 60601-2-52 : 2009-12	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds
IEC 60601-2-66 : 2015-06⊗	Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems
ISO 7176-1 : 2014-10	Wheelchairs - Part 1: Determination of static stability ISO 7176-1 : 1999-10⊗
ISO 7176-2 : 2001-06	Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs

ISO 7176-3 : 2012-12	Wheelchairs - Part 3: Determination of effectiveness of brakes ISO 7176-3 : 2003-04⊗
ISO 7176-4 : 2008-10	Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
ISO 7176-5 : 2008-06	Wheelchairs - Part 5: Determination of dimensions, mass and manoeuvring space
ISO 7176-6 : 2018-06	Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
ISO 7176-7 : 1998-05	Wheelchairs - Part 7: Measurement of seating and wheel dimensions
ISO 7176-8 : 2014-12	Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths ISO 7176-8 : 1998-07⊗
ISO 7176-9 : 2009-11	Wheelchairs - Part 9: Climatic tests for electric wheelchairs
ISO 7176-10 : 2008-11	Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
ISO 7176-14 : 2008-02	Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
ISO 7176-15 : 1996-11	Wheelchairs - Part 15: Requirements for information disclosure, documentation and labelling
ISO 7176-16 : 2012-12	Wheelchairs - Part 16: Resistance to ignition of postural support devices
ISO 7176-28 : 2012-10	Wheelchairs - Part 28: Requirements and test methods for stair-climbing devices
ISO 11199-1 : 1999-08	Walking aids manipulated by both arms - Requirements and test methods - Part 1: Walking frames
ISO 11199-2 : 2005-04	Walking aids manipulated by both arms - Requirements and test methods - Part 2: Rollators

ISO 11199-3 : 2005-04	Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables
ISO 11334-4 : 1999-02	Walking aids manipulated by one arm - Requirements and test methods - Part 4: Walking sticks with three or more legs
ISO 17966 : 2016-01	Assistive products for personal hygiene that support users - Requirements and test methods

Abbreviations used:

DIN	Deutsches Institut für Normung German Institute for Standardisation
EN	Europäische Norm European Standard
IEC	International Electrical Commission
ISO	International Organization for Standardization
Medical products, active	medizinisch-elektrische Geräte, medizinisch-elektrische Systeme und Komponenten Medical electrical equipment, medical electrical systems and components
VDE	Vorschriftenwerk Verband der Elektrotechnik Elektronik Informationstechnik e.V. Rules and regulations of the Association for Electrical Electronic & Information Technologies e.V.
⊗	Regulations retracted from the standardization in the area of active medical products, which are still applicable due to existing regulatory requirements out of Europe

[1] DIN EN ISO/IEC 17025:2018: General requirements for the competence of testing and calibration laboratories

[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

[3] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

[4] For the transition periods, see the list of harmonized standards on the EU homepage.