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	In-vitro-Diagnostik-(IVD-) Medizingeräte	Prüfung zum Nachweis der Übereinstimmung - Störaussendung - Störfestigkeit	I.S. EN IEC 61326-2-6 IEC 61326-2-6
	Vom Hersteller vorgelegte Informationen - Aufschriften - Bezeichnungen - Gebrauchsanweisung/Begleitpapiere	Prüfung auf Übereinstimmung	

Gegebenenfalls bestehende Ausschlüsse von Teilprüfungen einer Prüfung sind im Geltungsbereich der Akkreditierung nicht aufgeführt und müssen vom Labor bei Auftragsprüfung dem Auftraggeber mitgeteilt werden.

Die Akkreditierungsbegutachtung fand unter Berücksichtigung der normativen Verweise der europäischen Regelwerke (DIN EN) statt. Die normativen Verweise der internationalen Regelwerke (IEC, ISO) wurden nicht berücksichtigt, sofern die referenzierten internationalen Ausgabestände der Normen nicht explizit in der Anlage zum Bescheid ausgewiesen sind.

I.S. EN 60601-2-25:2015 (2015-11-10)	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs I.S. EN 60601-2-25:1995 & A1:1999 (2015-02-19) T - Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs
I.S. EN 60601-2-	

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I.S. EN IEC 60601-2-46:2019 (2019-12-05)	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables I.S. EN 60601-2-46:2011 (2011-08-23) T - Medical electrical equipment - Part 2-46: Particular requirements for basic safety and essential performance of operating tables I.S. EN 60601-2-46:2001 (2001-06-22) T - Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables
I.S. EN 60601-2-47:2015 (2015-06-09)	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems; I.S. EN 60601-2-47:2002 (2002-02-15) T - Medical electrical equipment - Part 2-47: Particular requirements for the safety including essential performance, of ambulatory electrocardiographic systems;
I.S. EN 60601-2-49:2015 (2015-11-10)	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment I.S. EN 60601-2-49:2002 (2002-02-15) T - Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
I.S. EN IEC 61326-2-6:2021 (2021-07-02)	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (in Verbindung mit I.S. EN IEC 61326-1:2021 (2021-07-02), solange eine gültige Akkreditierung hierfür besteht) I.S. EN 61326-2-6:2013 (2013-02-14) T - Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2012 (EQV)) (in Verbindung mit I.S. EN 61326-1:2013 (2013-02-14) T, solange eine gültige Akkreditierung hierfür besteht)
I.S. EN IEC 80601-2-26:2020 (2020-14-29)	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs; + AC:2021-10 (2021-11-15)

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I.S. EN 80601-2-35:2009 (2010-02-09)	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use + Amendment 11:2011 (2011-10-20) + Amendment 1:2016 (2017-01-23) I.S. EN 80601-2-35:2009 (2010-02-09) T - Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use
I.S. EN IEC 80601-2-49:2019 (2019-10-30)	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
IEC 60601-1-2 : 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests + Amendment 1 : 2020-09 IEC 60601-1-2 : 2007-03 T - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-25 : 2011-10	Medical electrical equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs IEC 60601-2-25 : 1993-03 + A1 : 1999-05 T - Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs
IEC 60601-2-26 : 2012-05 T	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs IEC 60601-2-26 : 2002-11 T - Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs
IEC 60601-2-34 : 2011-05	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blo(:)7()1p58 5

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CENELEC	European Committee for Electrotechnical Standardization
EN	Europäische Norm
IEC	International Electrotechnical Commission

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