Liste der angewandten Normen

Technologie Institut Medizin GmbH (TIM), August - Thyssen - Str. 30, D-56070 Koblenz, ist Hersteller des Produktes MIRUS™ Controller. Als registriertes Medizinprodukt der Klasse IIb nach MDD 93/42/EWG Regel 11 Anhang IX [Reg.-Nr. 44 232 117877; TÜV Nord Cert GmbH] erfüllt der MIRUS™ Controller die folgenden angewandten Normen.

Liste der angewandten Normen und Richtlinien, MIRUS™ Controller:

Kategorie	Bezugsnummer	Titel der Norm
Regulatory	93/42/EEC (option1)	Medical Device Directive
Regulatory	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
Safety	EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
Safety	EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
Safety	EN 60601-1-8:2007 + Cor.:2010 + A1:2013	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
Safety	IEC TS 62443-1-1:2009	Industrial communication networks. Network and system security - Part 1-1 Terminology, concepts and models
Safety	IEC TS 62443-2-1:2010	Industrial communication networks. Network and system security - Part 2-1 Establishing an industrial automation and control system security program
EMC/EMI	EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
Anaesthesia Systems	EN ISO 80601-2-13:2013	Medical electrical equipment - Particular requirements for the basic safety and essential performance of an anaesthetic workstation,
Anaesthesia Systems	EN ISO 5360:2016	Anaesthetic vaporizers - Agent-specific filling systems
Anaesthesia Systems	EN ISO 80601-2-55:2011	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
Respiratory monitoring	EN ISO 80601-2-12:2012	Medical electrical equipment- Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators (only resp. Monitoring)
Labelling	EN ISO 15223-1:2017	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
Labelling	EN 1041:2008 + A1:2013	Information supplied by the manufacture of medical devices

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Liste der angewandten Normen und Richtlinien, MIRUS™ Controller:

Kategorie	Bezugsnummer	Titel der Norm
Software	EN 62304:2006 + Cor.:2008 + A1:2015	Medical device software - Software life-cycle processes
Usability	EN 62366-1:2015 + AC:2015	Medical devices – Part 1: Application of usability engineering to medical devices
Biocompatibility	EN 10993-1:2009	Biological evaluation of medical devices-Part1: Evaluation and testing within a risk management system
Shock/ Mechanical	EN 60529:1991 + A1:2000 + A2:2013	Degrees of protection provided by enclosures (IP Code)
Hazardous substances	2011/65/EU	ROHS - Restriction of the use of certain hazardous substances Directive
Hazardous substances	1907/2006/EC	REACH - Registration, Evaluation, Authorization and Restriction of Chemicals
Hazardous substances	2012/19/EU	Waste Electrical and Electronic Equipment Directive
Guideline	Directive 2014/53/EU	DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

Wir, die Technologie Institut Medizin GmbH (TIM), erklären, dass die obige Liste der geltenden Normen und Richtlinien vollständig ist und die entsprechenden Standards angewendet wurden, soweit vom Umfang her zutreffend.

Koblenz, den 25.02.2022

Prof. Ing. Thomas P.Kriesmer

//: Ende des Dokumentes.

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