Declaration on “Conformity with Standards”

Manufacturer

Name:	Siemens Healthcare GmbH
Address:	Henkestr. 127 91052 Erlangen Germany
Single Registration Number (SRN):	DE-MF-000006122

Product Identification

Product/Trade Name	MAGNETOM Vida
Model	11060815 (made in Germany) 11516152 (made in China)
Basic UDI-DI	0405686900125UQ
UDI-DI	04056869039176 (made in Germany) 04056869260143 (made in China)

Nomenclature Code

GMDN Code	37654
GMDN Term	Full-body MRI system, superconducting magnet

We declare the compliance of the above medical device(s) with the standards listed on the following page(s).

Place and date: Erlangen, December 1, 2023

Siemens Healthcare GmbH

Signature

Electronically signed by: Michael Heinold Reason: i.V. Date: Dec 1, 2023 13:03 GMT+1	*Electronically signed by: Joerg Teiche Reason: i.V. Date: Dec 1, 2023 10:17 GMT+1*

Name

Michael Heinold	Jörg Teiche
Head of Supply Chain Management MR	Head of Quality Magnetic Resonance

For conditions of warranty and liability please refer to the General Conditions of Sale.

List of Standards

Reference No	Title of the standard
IEC 60601-1:2012 EN 60601-1:2006 + Cor.:2012 + A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-2-33:2010/A1:2013 /A2:2015 EN 60601-2-33:2010/A2:2015	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
IEC 60601-1-2:2014 EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2010 + A1:2013 EN 60601-1-6:2010 + A1:2015	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability
IEC 62304:2006+A1:2015 EN 62304:2006+Cor.:2008+ A1:2015	Medical device software - Software lifecycle processes
IEC 62366-1:2020 EN 62366-1:2021	Medical devices - Application of usability engineering to medical devices
EN 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
ISO 15223-1:2021 EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
ISO 10993-1:2018 EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 14971:2019 EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
ISO 13485:2016 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14155:2020 EN ISO 14155:2020	Clinical investigation of medical devices for human subjects -- Good clinical practice
IEC 60825-1:2014 EN 60825-1:2014	Safety of laser products - Part 1: Equipment classification, requirements, and user's guide
IEC 62353:2014 EN 62353:2014	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment