

Declaration of Conformity with Standards

Manufacturer Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany

Single Registration Number DE-MF-000006122

Facility Siemens Healthcare GmbH
Magnetic Resonance (MR)
Henkestr. 127
91052 Erlangen
Germany

Product Identification
Product/Trade Name: MAGNETOM Sola Fit
Model: 11410482
Basic UDI-DI: 0405686900125UQ
UDI-DI: 04056869245195

Nomenclature Code
GMDN Code: 37654
GMDN Term: Full-body MRI system, superconducting magnet
CND Code: Z110501
CND Term: Magnetic Resonance Imaging System

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

Place and date Erlangen, May 25, 2022

Siemens Healthcare GmbH

 ppa. Arthur Kaindl arthur.kaindl@siemens-healthineers.com	<small>Electronically signed by: Arthur Kaindl Reason: I am approving this document Date: May 25, 2022 16:59 GMT+2</small>	 joerg.teiche@siemens-healthineers.com	<small>Electronically signed by: Jörg Teiche Reason: I am approving this document Date: May 25, 2022 14:01 GMT+2</small>
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Signature

Name

Dr. Arthur Kaindl
Executive Vice President Magnetic Resonance

Jörg Teiche
Head of Quality Magnetic Resonance

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

List of Standards

Standard / Edition	Title
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 62366-1:2015 EN 62366-1:2015	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 10993-1:2009 EN ISO 10993-1:2009+AC2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 14971:2007 EN ISO 14971:2012 EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO 13485:2016 EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14155:2020 EN ISO 14155: 2011	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