EU DECLARATION OF CONFORMITY

of Regulation (EU) 2017/745

Manufacturer

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

Facility

Name:	Siemens Healthineers AG Magnetic Resonance (MR)
Address:	Henkestr. 127 91052 Erlangen Germany
Name:	Siemens Healthineers AG Magnetic Resonance (MR)
Address:	Allee am Röthelheimpark 2 91052 Erlangen Germany
Name:	Siemens Shenzhen Magnetic Resonance Ltd.
Address:	Siemens MRI Center Gaoxin C, Ave. 2nd Hi-Tech Industrial Park 518057 Shenzhen Peoples Republic of China

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Product Identification

Product/Trade Name:	MAGNETOM Sola
Model:	11291455 (made in Germany) 11410231 (made in China)
Basic UDI-DI:	04056869OO125UQ
UDI-DI:	04056869164809 (made in Germany) 04056869217864 (made in China)

Nomenclature Code

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

Classification

Risk Class:	Class IIa (according to rules 10 and 11 Annex VIII Medical Device Regulation (EU) 2017/745)

Intended Purpose Statement under Regulation (EU) 2017/745:

Magnetic Resonance Imaging Systems

We declare that the above medical device is in conformity with the following legislation(s):

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices

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The conformity of the quality management system according to Annex IX and Article 52 is certified by the following notified body:

TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 Munich
Germany

The identification number of the notified body for implementation of the procedure set out in Annex IX and Article 52 to the above regulation is: 0123
Identification of EC Certificate: G10 091596 0052 Rev. 01
Reference to Common Specifications: /

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Relevant Harmonized Standard: EN IEC 63000:2018

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare GmbH.
This declaration supersedes any declaration issued previously for the same product.

Place and date Erlangen, December 1, 2023

Siemens Healthcare GmbH

Signature

Electronically signed by: Michael Heinold Reason: i.V. Date: Dec 1, 2023 09:42 GMT+1	Electronically signed by: Joerg Teiche Reason: i.V. Date: Dec 1, 2023 09:14 GMT+1

Name

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

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