Declaration of Conformity with Standards

Manufacturer

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany

Single Registration Number DE-MF-000006122

Facility

Siemens Healthineers AG
Digital & Automation (D&A)
Siemensstr. 1,
91301 Forchheim,
Germany

Product Identification

Product/Trade Name	*syngo*.via
Model	11582847
Basic UDI-DI	0405686901978WU
UDI-DI	04056869285801

Nomenclature Code

GMDN Code:	57812
GMDN Term:	Radiology DICOM image processing application software
EMDN Code:	Z11069092
EMDN Term:	VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS - MEDICAL DEVICE SOFTWARE

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

Place and date Forchheim, April 4th, 2024

Siemens Healthcare GmbH

Signature

Name	Christian Zapf	Thomas Frank
	Head of Business Line,	*Head of Quality,*
	Digital & Automation (D&A)	*Digital & Automation (D&A)*

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

List of Standards

Reference No	Title of the standard
EN ISO 14971:2019+A11:2021 / ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62304/A1:2015/ IEC 62304:2006+AMD1:2015	Medical device software - Software life cycle processes
IEC 82304-1:2016 (Ed 1 2016-10)	Health software - Part 1: General requirements for product safety
EN 62366-1/A1:2020-08 / IEC 62366-1/A1 :2020-06 Edition 1.1	Medical device - Part 1: - Applicability of usability engineering in medical devices
EN ISO 13485:2016 + AC:2018 + A11:2021 / ISO 13485:2016	Medical devices - Quality Management Systems - Requirements for regulatory purposes
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 20417:2021 EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer

EU DECLARATION OF CONFORMITY

Manufacturer

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

Facility

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Classification

Risk Class: Class *IIb* (according to rule 11 of Annex VIII Medical Device Regulation (EU) 2017/745)

For Class IIb:

Intended Purpose Statement as stated on the EC Certificate:

Software solutions intended to process, communicate, display, read, and archive medical data for informing and driving clinical management

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

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 Muenchen
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: *'/'*

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 *Siemens Healthcare GmbH* Forchheim, December 1st, 2023

Signature

Name

Christian Zapf
Head of Business Line,
Digital & Automation (D&A)

Thomas Frank
Head of Quality,
Digital & Automation (D&A)

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