Declaration of Conformity with Standards

Manufacturer	*Siemens Healthcare GmbH* *Henkestr. 127* *91052 Erlangen* *GERMANY*
Single Registration Number	N.A
Facility	*Siemens Healthcare GmbH* *SYNGO (SY)* *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
CND Code	Z11069082
CND Term	VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS - 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 19, 2021*

Siemens Healthcare GmbH

Signature

Name	*Christian Zapf* *(Head of SYNGO)*	Thomas Frank *(Head of SYNGO Quality Management)*

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

Digitally signed by Belan Irina
Date: 2022.12.16 15:14:20 EET
Reason: MoldSign Signature
Location: Moldova

List of Standards

Reference No	Title of Standard
EN ISO 14971:2012 / ISO 14971:2007	Medical devices - Application of risk management to medical devices
EN 62304:2006/AC:2008 / IEC 62304:2006-05+AMD1:2015-06	Medical device software - Software life cycle processes
IEC 82304-1:2016 (Edition 1.0, 2016-10)	Health software – Part 1: General requirements for product safety
EN 62366:2008 (no A1) / IEC 62366-1:2015-02	Medical device – Applicability of usability engineering in medical devices
EN ISO 13485:2016/AC:2018 / ISO 13485:2016	Medical devices – Quality Management Systems - Requirements for regulatory purposes
EN ISO 15223-1:2016 / ISO 15223-1 Third Edition, Corrected Version 2017-03	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices