

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*

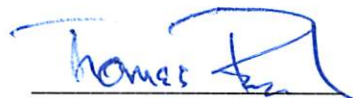
CND Code *Z11069082*
CND Term *VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS -
SOFTWARE*

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.

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