

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*

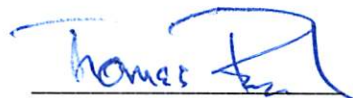
CND Code *Z11069082*
CND Term *VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS - SOFTWARE*

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