Declaration of Conformity with Standards

Manufacturer	Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany
Single Registration Number	DE-MF-000006122
Facility	Siemens Healthcare GmbH Computed Tomography (CT) Siemensstr. 1 91301 Forchheim Germany
Product Identification	
Product/Trade Name	**SOMATOM go.Top** VA40
Model	11061640
Basic UDI-DI	0405686900117UR
UDI-DI	04056869151571
Nomenclature Code	
GMDN Code	37618
GMDN Term	X-ray system, diagnostic, computed tomography, full body
CND Code	Z11030605
CND Term	COMPUTED TOMOGRAPHY SCANNING SYSTEMS - >= 64 AND < 128 SLICES

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

Place and date: Forchheim, 28. 07. 21

Siemens Healthcare GmbH

Signature

Name	Dr. Philipp Fischer (Head of Unit CT)	Dr. Markus Nagel (Head of Unit CT 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 10:54:02 EET
Reason: MoldSign Signature
Location: Moldova

List of Standards

Reference No	Title of the standard
IEC 60601-1:2005 IEC 60601-1:2005/AMD1:2012	General requirements for basic safety and essential Performance
IEC 60601-1-2:2007 IEC 60601-1-2:2014	General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-28:2017	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-1-3:2008 IEC 60601-1-3:2008/AMD1:2013	General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2010 IEC 60601-1-6:2010/AMD1:2013	General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-44:2009 IEC 60601-2-44:2009/AMD1:2012 IEC 60601-2-44:2009/AMD2:2016	Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
IEC 60825-1:2014	Safety of laser products – Part 1: Equipment classification and requirements
IEC 61223-2-6:2006	Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment
IEC 61223-3-5:2004	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment; Corrigendum 1
IEC 62304:2006+AMD1:2015	Medical device software - Software life cycle processes
IEC 62366-1:2015	Medical devices – part 1: Application of usability engineering to medical devices
IEC 62563-1:2009 +AMD1:2016	Medical electrical equipment - Medical image display systems – Part 1: Evaluation methods
IEC 62985:2019	Methods for calculating Size Specific Dose Estimate (SSDE) on Computed Tomography
IEC 80001-1:2010	Application of risk management for IT Networks incorporating medical devices - Part 1: Roles, responsibilities and activities
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices