Declaration on “Conformity with Standards”

Manufacturer

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

Product Identification

Product/Trade Name	**SOMATOM go.Top**
Software Version	VB20
Model	11061640
Basic UDI-DI	04056869001170R
UDI-DI	04056869151571

Nomenclature Code

EMDN Code	Z11030605
EMDN Term	COMPUTED TOMOGRAPHS - 64 LAYERS OR MORE BUT LESS THAN 128 LAYERS
GMDN Code	37618
GMDN Term	Full-body CT system

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

Place and date Forchheim, 14.04.2025

Siemens Healthcare GmbH

Signature

P. Fi

Electronically signed by:
Philipp Fischer
Reason: I am approving this document
Date: Apr 14, 2025 11:29 GMT+2

Electronically signed by:
Markus Nagel
Reason: I am approving this document
Date: Apr 17, 2025 11:33 GMT+2

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: 2025.05.23 11:09:28 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

List of Standards

Standard / Edition	Title of the standard
ISO 20417:2021+ Corr1:2021	Medical devices - Information to be supplied by the manufacturer
IEC 60529:1989+A1:1999+A2:2013	Degrees of protection provided by enclosures (IP code)
IEC 60601-1:2005+Cor1:2006+ Cor2:2007+A1:2012+A1:2012/Cor1:2014+A2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 + A1:2020	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-3:2008+A1:2013+A2:2021	Medical electrical equipment – Part1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2010+A1:2013+A2:2020	Medical electrical equipment – Part1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-44: 2009 + A1:2012+ A2:2016	Medical electrical equipment - Part 2-44: 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 62304:2006 + A1:2015	Medical devices software – Software lifecycle processes
IEC 62353:2014	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
IEC 62366-1:2015 + Corr1:2016 + AMD1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 80001-1:2021	Application of risk management for IT-networks incorporating medical devices - Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software
ISO/HL7 10781:2015	Health Informatics - HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM)
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 12052:2017	Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management
ISO 14971:2019	Medical devices – Application of risk management to medical devices / Corrected and reprinted in 2007-10.
ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
ISO 17664-2:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices

Standard / Edition	Title of the standard
IEC TS 60601-4-2:2024	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC/TR 80001-2-2:2012	Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO/ IEC 27001:2013+Cor1:2014 + Cor2:2015	Information technology - Security techniques - Information security management systems - Requirements
IEC 81001-5-1: 2021	Health Software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product lifecycle
ISO/IEC 27005:2011	Information technology - Security techniques - Information security risk management
EN 60695-11-10:2013	Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods