

EU DECLARATION OF CONFORMITY

of Regulation (EU) 2017/745

Manufacturer

Name: Siemens Healthcare GmbH
Address: Henkestr. 127
91052 Erlangen
Germany

Single Registration
Number (SRN): DE-MF-000006122

Facility

Name: Siemens Healthineers AG
Computed Tomography (CT)

Address 1: Siemensstr. 1
91301 Forchheim
Germany

Address 2: Rittigfeld 1
91301 Forchheim
Germany

Product Identification

Product/Trade Name: **SOMATOM go.Top**
Model: 11061640
Software Version: VB10
Basic UDI-DI: 0405686900117UR
UDI-DI: 04056869151571

Nomenclature Code

GMDN Code: 37618
GMDN Term: Full-body CT system

Classification

Risk Class: Class IIb (according to rule 10 Annex VIII Medical Device Regulation (EU) 2017/745)

Intended Purpose Statement under Regulation (EU) 2017/745:

Computed tomography system intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

We declare that the above medical device is in conformity with the following legislation(s):

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices

The conformity of the quality management system according to Annex IX and Article 52 is certified by the following notified body:

TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 Muenchen
Germany

The identification number of the notified body for implementation of the procedure set out in Annex IX and Article 52 to the above regulation is: 0123

Identification of EC Certificate: G10 091596 0052

Reference to Common Specifications: /

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

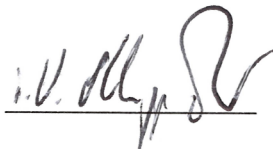
Relevant Harmonized Standard: EN IEC 63000:2018

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare GmbH.

Place and date Forchheim, 05. Dez. 2023

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.