

# 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

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## Facility

Name: Siemens Healthineers AG  
Computed Tomography (CT)

Address 1: Siemensstr. 1  
91301 Forchheim  
Germany

Address 2: Rittigfeld 1  
91301 Forchheim  
Germany

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## 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.

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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

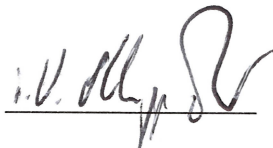
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This declaration of conformity is issued under the sole responsibility of Siemens Healthcare GmbH.

Place and date Forchheim, **05. Dez. 2023**

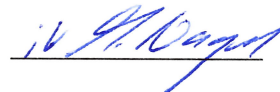
Siemens Healthcare GmbH

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.