

EU DECLARATION OF CONFORMITY

Manufacturer

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

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

Facility

Name: Siemens Healthcare GmbH
Computed Tomography (CT)

Address: Siemensstr. 1
91301 Forchheim
Germany

Product Identification

Product/Trade Name: **syngo.CT Dual Energy**
Model: 11546460
Software Version: VB71
Basic UDI-DI: 0405686900118UT
UDI-DI: 04056869966922

Nomenclature Code

GMDN Code: 40867
GMDN Term: CT system application software

Classification

Risk Class: Class IIa (according to rule 11 Annex VIII Medical Device Regulation (EU) 2017/745)

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: /

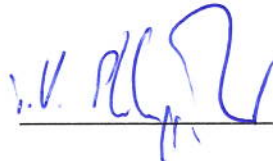
This declaration of conformity is issued under the sole responsibility of Siemens Healthcare GmbH.

Place and date

Forchheim, 02.08.22

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.