EU Declaration of Conformity

SIEMENS Healthineers

Manufacturer

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

Facility

Name:	Siemens Healthineers AG Advanced Therapies
Address:	Siemensstr. 1 91301 Forchheim GERMANY

Product Identification	see next page
Device Group	Z110301 - DIGITAL ANGIOGRAPHIC SYSTEMS
Classification	Class IIb (according to rule 10 Annex VIII Medical Device Regulation (EU) 2017/745)
Intended Purpose	Angiography system intended for angiography- and fluoroscopic based procedures
Basic UDI-DI	0405686900145UW
Product Version	VD12

We declare that the above medical devices are 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 Munich
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
Certificate number of issued certificate:	G10 091596 0052
Reference to Common Specifications:	n. a. – no Common Specification available for this product

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.
This declaration supersedes any declaration issued previously for the same products.

Place and date: Forchheim, December 01, 2023

Siemens Healthcare GmbH

Signature

Name

ppa. C. Bertram
Carsten Bertram
President of
Advanced Therapies

i.V. Dr. Denger
Dr. Christian Denger
Head of Quality
Advanced Therapies

For conditions of warranty and liability please refer to the General Conditions of Sale.

SIEMENS Healthineers

Product identification

Product/Trade Name	Model	UDI-DI	UDI-PI	GMDN Code	GMDN Term
Artis Q floor / Artis Q floor	10848280	04056869009971	Serial Number 104000 onwards	37623	Stationary angiographic x-ray system, digital
Artis Q ceiling / Artis Q ceiling	10848281	04056869009988	Serial Number 110000 onwards	37623	Stationary angiographic x-ray system, digital
Artis Q biplane / Artis Q biplane	10848282	04056869009995	Serial Number 122000 onwards	37623	Stationary angiographic x-ray system, digital
Artis Q.zen floor / Artis Q.zen floor	10848353	04056869010014	Serial Number 105500 onwards	37623	Stationary angiographic x-ray system, digital
Artis Q.zen ceiling / Artis Q.zen ceiling	10848354	04056869010021	Serial Number 111500 onwards	37623	Stationary angiographic x-ray system, digital
Artis Q.zen biplane / Artis Q.zen biplane	10848355	04056869010038	Serial Number 123500 onwards	37623	Stationary angiographic x-ray system, digital
Artis zee floor / Artis zee floor	10094135	04056869010045	Serial Number 139000 onwards	37623	Stationary angiographic x-ray system, digital
Artis zee ceiling / Artis zee ceiling	10094137	04056869010052	Serial Number 150000 onwards	37623	Stationary angiographic x-ray system, digital
Artis zee biplane / Artis zee biplane	10094141	04056869010069	Serial Number 156000 onwards	37623	Stationary angiographic x-ray system, digital
Artis zee multi-purpose / Artis zee multi-purpose	10094139	04056869010076	Serial Number 159000 onwards	37623	Stationary angiographic x-ray system, digital