EU Declaration of Conformity

SIEMENS Healthineers

Manufacturer

Name:	*Siemens Healthcare GmbH*
Address:	*Henkestr. 127* *91052 Erlangen* *GERMANY*
Single Registration Number (SRN):	*n. a. - EUDAMED database not yet available*

Facility

Name:	*Siemens Healthcare GmbH* *Advanced Therapies*
Address:	*Siemensstr. 1* *91301 Forchheim* *GERMANY*

Product Identification	*see next page*
Device Group	*Z11039017 - MOBILE RADIOGRAPHIC/FLUOROSCOPIC UNITS*
Classification	*Class IIb (according to rule 10 Annex VIII Medical Device Regulation (EU) 2017/745)*
Intended Purpose	*Mobile X-ray system intended for angiography- and fluoroscopic-based procedures*
Basic UDI-DI	*0405686900147V2*
Product Version	*VA30*

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 50581:2012; 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 21, 2020

Siemens Healthcare GmbH

Signature: i. V. Reinmar Killmann i. V. S

Name:

Dr. Reinmar Killmann
VP of Project & Portfolio Management
Advanced Therapies

Siegfried Quinger
VP of Quality
Advanced Therapies

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

Product/Trade Name	Model	UDI-DI	UDI-PI	GMDN Code	GMDN Term
Cios Flow / Cios Flow	11108110	04056869246628	Serial Number 80001 onwards	37649	Portable general-purpose fluoroscopic x-ray system, digital
Cios Alpha / Cios Alpha	11105200	04056869153490	Serial Number 40300 onwards	37649	Portable general-purpose fluoroscopic x-ray system, digital
Cios Spin / Cios Spin	10308194	04056869153506	Serial Number 50400 onwards	37649	Portable general-purpose fluoroscopic x-ray system, digital