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	Z12050701 - Complete Cardiography Systems
Classification	Class IIb (according to rule 10 Annex VIII Medical Device Regulation (EU) 2017/745)
Intended Purpose	Recording system intended for physiological, hemodynamic, and electrophysiological monitoring.
Basic UDI-DI	0405686900144UU
Product Version	VD1

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 Rev. 01
Reference Common Specifications:	n. a. as 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	Carsten Bertram President Advanced Therapies	Dr. Christian Denger Head of Quality Advanced Therapies

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

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Product identification

Product/Trade Name	Model	UDI-DI	UDI-PI	GMDN Code	GMDN Term
Sensis Vibe Hemo	11007641	04056869010199	Serial Number 106000 onwards	10980	Cardiac catheterization laboratory computer
Sensis Vibe Combo	11007642	04056869010205	Serial Number 126000 onwards	10980	Cardiac catheterization laboratory computer