EU Quality Management Certificate

This is to certify that the company

synedra information technologies GmbH

Feldstraße 1/13
6020 Innsbruck
Austria

SRN: AT-MF-000000903

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	342203 MDR2017Q
Certificate ID	1000186556
Effective date	2024-07-12
Expiry date	2026-12-01
Frankfurt am Main,	2024-07-12

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: AT-MF-000000903
Certificate ID: 1000186556

Device categories and variants covered by this certificate:

Device category:	**MDA 0315 - Software**
Product name:	synedra AIM - Software
Risk classification:	IIb
Basic-UDI-DI:	912010070aimHG
Intended purpose:	synedra AIM is a modularly structured software solution for the hospital-wide acquisition, archiving, distribution, and diagnosis of medical multimedia patient data and thus provides essential information for the treatment of all patient groups. This information shall be used to support the following medical purposes: diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, injury or disability.

Device category:	**MDA 0315 - Software**
Product name:	synedra View Professional - Software
Risk classification:	IIb
Basic-UDI-DI:	912010070viewproW6
Intended purpose:	synedra View Professional is a viewer intended to be used for the viewing and manipulation of radiology and clinical image and multimedia data as well as for diagnostic imaging and thus provides essential information for the treatment of all patient groups. This information shall be used to support the following medical purposes: diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, injury or disability.

Examinations and tests performed:

420_11d_Bericht_MED_AZ342203-A207905MED-20210630 from 16.07.2021
342203-A207905MED_420_12d_Bericht_Produktprüfung-20211208.docx from 10.12.2021
342203_A209901MED_420_12d_Bericht_Produktprüfung-20220126 from 01.02.2022
342203_A210828MED_01 from18.07.2022
342203_A212937MED_02 from 31.08.2023
342203_A215181MED_01 from 05.07.2024

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2021-12-02	170773801	Softwareupdate zu Version 21 “Argos”
02	2022-02-24	170779445	Softwareupdate zu Version 22 “Niobe”
03	2022-07-25	170780824	Change of Certificate Template
04	2024-05-23	1000169586	Softwareupdate zu Version 24 “Herakles”