EU Technical Documentation Assessment Certificate

This is to certify that the company

synedra information technologies GmbH

Feldstraße 1/13
6020 Innsbruck
Austria

SRN: AT-MF-000000903

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

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

For placing medical devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Certificate registration no.	342203 MDR2017B
Certificate ID	170780826
Effective date	2022-07-25
Expiry date	2026-12-15
Frankfurt am Main,	2022-07-25

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)

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: AT-MF-000000903
Certificate ID: 170780826

Device categories and variants covered by this certificate:

Device category:	**Medical universal archive**
Product name:	synedra AIM - Software
Models:	Version 22 Niobe
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:	**PACS Viewer**
Product name:	synedra View Professional - Software
Models:	Version 22 Niobe
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:
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

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	2021-12-16	170775968	Softwareupdate to Version 21 “Argos”
02	2022-02-24	170779401	Softwareupdate to Version 22 “Niobe”