



# 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	1000256090
Effective date	2025-07-10
Expiry date	2026-12-01
Frankfurt am Main,	2025-07-10



**DQS Medizinprodukte GmbH**

Heinrich von Mettenheim  
Managing Director



Device categories and variants covered by this certificate:

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.



Annex to EU Quality Management Certificate  
SRN of Manufacturer: AT-MF-000000903  
Certificate ID: 1000256090

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 dated 16.07.2021  
342203-A207905MED\_420\_12d\_Bericht\_Produktprüfung-20211208.docx dated 10.12.2021  
342203\_A209901MED\_420\_12d\_Bericht\_Produktprüfung-20220126 dated 01.02.2022  
342203\_A210828MED\_01 dated 18.07.2022  
342203\_A212937MED\_02 dated 31.08.2023  
342203\_A215181MED\_01 dated 05.07.2024  
342203\_A217568MED\_01 dated 01.07.2025

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	Software update to version 21 "Argos"
02	2022-02-24	170779445	Software update to version 22 "Niobe"
03	2022-07-25	170780824	Change of Certificate Template
04	2024-05-23	1000169586	Software update to version 24 "Herakles"
05	2024-07-12	1000186556	Software update to version 25 "Rhea"