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. Limitations to this certificate are listed in the Annex.

Certificate registration no.	342203 MDR2017Q
Certificate ID	170780824
Effective date	2022-07-25
Expiry date	2026-12-01
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)

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 this certificate can only be verified by the QR-code.

420.90 Version 4.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: AT-MF-000000903
Certificate ID: 170780824

Device categories covered by this certificate:

Device category:	**Medical universal archive**
Risk classification:	IIb
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**
Risk classification:	IIb
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

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

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"