



EU Quality Management Certificate



This is to certify that the company



A Siemens Healthineers Company

ITH icoserve technology for healthcare GmbH

Innrain 98
6020 Innsbruck
Austria

SRN: AT-MF-000001995

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.	549281 MDR2017Q
Certificate ID	1000169848
Effective date	2024-04-25
Expiry date	2028-05-31
Frankfurt am Main,	2024-04-25



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.



Annex to EU Quality Management Certificate
SRN of Manufacturer: AT-MF-000001995
Certificate ID: 1000169848

Device categories and variants covered by this certificate:

Device category: **MDA 0315 - Software**
Product name: syngo.share view diagnostic
Risk classification: IIa
Basic-UDI-DI: 4260498940001ZT
Intended purpose: syngo.share view diagnostic is software to be used in clinical image and result distribution for diagnostic purposes by trained professionals such as physicians, technologists and nurses, and provides standardized generic interfaces to connect to medical devices without controlling or altering their functions. syngo.share view diagnostic provides access to data from connected systems (such as Vendor-Neutral Archives, Picture Archiving and Communication Systems, DICOM archives, XDS/-I Affinity Domains, Electronic Medical Record Systems, Clinical Information Systems) and from local filesystems for the electronic display of data for the purpose of diagnoses, medical findings, and annotations.

Device category: **MDA 0315 - Software**
Product name: syngo.share webview diagnostic
Risk classification: IIa
Basic-UDI-DI: 4260498940001ZT
Intended purpose: syngo.share webview diagnostic is a web application to be used in clinical image and result distribution for diagnostic purposes by trained professionals such as physicians, technologists and nurses, and provides standardized generic interfaces to connect to medical devices without controlling or altering their functions. syngo.share webview diagnostic provides access to data from connected systems (such as Vendor-Neutral Archives, Picture Archiving and Communication Systems, DICOM archives, XDS/-I Affinity Domains, Electronic Medical Record Systems, Clinical Information Systems) and from local filesystems for the electronic display of data for the purpose of diagnoses, medical findings, and annotations.

Examinations and tests performed:

549281 A210985MED MDR2017Q dated 2023-03-10
549281 A210985MED MDR2017B dated 2022-12-11

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	2023-06-01	1000120493	new certificate template