EU Quality Management Certificate

This is to certify that the company

Vepro AG Germany

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64319 Pfungstadt
Germany

SRN: DE-MF-000018755

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.	527544 MDR2017Q
Certificate ID	1000208825
Effective date	2025-09-24
Expiry date	2030-09-23
Frankfurt am Main,	2025-09-24

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

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

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.

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420.90 Version 7.0

Device categories and variants covered by this certificate:

Device category:	**MDA 0315**
Product name:	EMR Manager
Risk classification:	IIa
Basic-UDI-DI:	426075569EMRMANAGERCA
Intended purpose:	the EMR Manager is software for importing, editing, archiving, managing, and reproducing data generated by external modalities and transmitted in DICOM format.
	The EMR Manager is not intended to support or sustain human life. It does not transmt or cause injury or illness.
	It may only be used by medical professionals, who must be trained in the system by the operator prior to use.
	The data can be imported in analog or digital format.
	The images can be displayed on monitors, edited (e.g., contrast, zoom), archived (e.g., hard drive, DVD), reproduced (e.g., printer), and transmitted via data communication.
	The EMR Manager does not perform independent clinical diagnoses or treatments and does not influence diagnostic devices.
	The EMR Manager does not maintain any independent data or specifications for the treatment, it merely supports the medical specialist in the assessment.
	The EMR Manager merely provides the images generated by external modalities, which must then be output, processed and assessed by qualified medical professionals.

Examinations and tests performed:
527544 A216264MED dated 2025-08-28
527544 A216266MED EMR Manger dated 2025-02-24

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
n/a	n/a	n/a	n/a