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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 103842 0004 Rev. 00

Manufacturer:

Cablon Medical B.V.
Klepelhoek 11
3833 GZ Leusden
THE NETHERLANDS

SRN Manufacturer - NL-MF-000002582

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 103842 0004 Rev. 00

Report No.: 713269840

Valid from: 2024-02-06
Valid until: 2029-02-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-02-06

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G10 103842 0004 Rev. 00

Classification:	Class IIb
Device Group:	Z11019082 - VARIOUS RADIOTHERAPY AND RADIOSURGERY INSTRUMENTS - SOFTWARE ACCESSORIES
Intended Purpose:	The Theraview software is used in radiation therapy clinics to acquire Megavoltage (MV) and/ or kiloVoltage (kV) images by means of an imaging device, using one of the Cablon Medical accessories EPID, DAR, eDAR or TBI, and perform image registration (i.e. image matching, tracking) or import match results, in order to accurately set up and position patients for treatment.
Classification:	Class IIa
Device Group:	Z11039021 - RADIOGRAPHY VIDEO ACQUISITION SYSTEMS
Intended Purpose:	-
Classification:	Class IIb
Device Group:	Z120112 - PATIENT POSITIONING INSTRUMENTS
Intended Purpose:	The Theraview Couch Setup Assistant (TCSA) is used in radiation therapy clinics to accurately set up and position patients prior to treatment in a reproducible way by means of a couch controller.
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2024-02-06	713269840	- Initial issuance

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