ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Danmark

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

No. G11DK 128750 0001 Rev. 00

Manufacturer:

machineMD AG
Weyermannsstrasse 36
3008 Bern
SWITZERLAND

SRN Manufacturer - CH-MF-000041378

Authorized Representative:

MED-RAS GmbH
Eichenallee 8H, 21521 Wohltorf, GERMANY

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.
Details on devices covered by the quality management system are described on the following page(s). The Report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

If class IIa or class IIb devices are covered by this certificate, The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes a further assessment of the technical documentation on the basis of representative samples.

If class Is or class Im devices are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions, or conformity of the devices with the metrological requirements.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11DK 128750 0001 Rev. 00

Report No.: 05 machineMD CH-MF-000041378 - 5.2.02 - 735200624 Project Conformity Assessment Summary Report, ver. 5

Valid from: 2024-10-07
Valid until: 2029-10-06

Malou Hjæresen
Head of Certification

Issue date: 2024-10-08

TÜV SÜD Danmark ApS, Strandvejen 125, 2900 Hellerup, Denmark is Notified Body with identification no. 2443.

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Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

No. G11DK 128750 0001 Rev. 00

Device(s) covered by this Certificate:

Risk Classification: Class IIa
Device Group: MDA 0204
Basic description: NEOS™ Head mounted display & Software

The validity of this certificate depends on conditions and/or is limited to the following: N/A

Revision History:

Rev.	Dated	Report	Description
00	2024-10-07	05 machineMD CH-MF-000041378 - 5.2.02 - 735200624 Project Conformity Assessment Summary Report, ver. 5	Initial issuance

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