EU Quality Management System Certificate FI23/00000046

The management system of

Rhyk Technologies GmbH

Address: Rhyk Technologies GmbH, Bahnhofsvorplatz 1, 50667, Cologne, Germany, SRN: DE-MF-000009068

has been assessed and certified as meeting the requirements of

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

For the following products
Nervous and medullary system devices

Certification is based on decision FI23/08126P0
Previous certificate number: N/A
Change in between this certificate and previous one: N/A
Devices covered, risk classification, conditions or limitations, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 27 September 2023 until 26 September 2026 and remains valid subject to satisfactory surveillance audits.
Issue 1 Certified since 27 September 2023
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Seppo Vahasalo, NB Manager

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Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland
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Rhyk Technologies GmbH

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Issue 1
Sites
Rhyk Technologies GmbH Bahnhofsvorplatz 1 50667, Cologne Germany

Rhyk Technologies GmbH

Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

Attachment 1 of Issue 1

Device or Device Group, EMDN Code	Risk Class	Identification Details
EMDN N99 - Nervous and medullary system devices - other	IIa	Rhyk NEO

The certification decision is based on the following:

Report Identification and Date
Audit report: Rhyk_V1_S2_FPMDREG3019 - MD Audit Report Ver E_v1 (2023-09-26) TDA report: Rhyk_V1_S2_FPMDREG3019 - MD Audit Report Ver E_v1 (2023-09-26)

Conditions for or limitation to the validity of the certificate
PMCF investigation to be planned and conducted for treatment results that have been obtained with the Rhyk NEO device.

EU Authorised Representative
N/A