

EU Quality Management System Certificate FI23/00000046

The management system of

Rhyk Technologies GmbH

The SGS logo consists of the letters 'SGS' in a bold, sans-serif font. A vertical line is positioned to the right of the 'S', and a horizontal line is positioned below the 'S' and 'G', forming a partial frame around the letters.

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.

A handwritten signature in blue ink, appearing to read 'Seppo Vahasalo', is written over a horizontal line.

Authorised by

Seppo Vahasalo, NB Manager

SGS FIMKO OY

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)

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

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Rhyk Technologies GmbH

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

| Attachment 1 of Issue 1 | | | | | | | | |
|--|------------|------------------------|-----------------------------------|------------|------------------------|---|-----|----------|
| <table border="1"> <thead> <tr> <th>Device or Device Group, EMDN Code</th> <th>Risk Class</th> <th>Identification Details</th> </tr> </thead> <tbody> <tr> <td>EMDN N99 - Nervous and medullary system devices - other</td> <td>Ila</td> <td>Rhyk NEO</td> </tr> </tbody> </table> | | | Device or Device Group, EMDN Code | Risk Class | Identification Details | EMDN N99 - Nervous and medullary system devices - other | Ila | Rhyk NEO |
| Device or Device Group, EMDN Code | Risk Class | Identification Details | | | | | | |
| EMDN N99 - Nervous and medullary system devices - other | Ila | 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 | | | | | | | | |

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