EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Neoventa Medical AB

Norra Ågatan 32, SE- 431 35 Mölndal, Sweden

Manufacturer SRN: SE-MF-000001402

Scope:

- Non-active instruments

Certificate Number:
28620165315

Revision:
00

Initial Certification Date:
24 January 2024

Certificate Decision Date:
24 January 2024

Certificate Issue Date:
24 January 2024

Certificate Expiry Date:
16 March 2028

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**D00356-01 Neoventa Medical AB Goldtrace Fetal Spiral Electrode (FSE)**
Audit Report Reference	**Stage 1 audit ACTY-2023-658566**
	Stage 2 audit ACTY-2023-122550

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620165315

Revision:
00

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MDR – Decision Report

Certificate No: 28620165315
Date: 24 January 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Neoventa Medical AB
Attn: Johan Sundberg
Norra Ågatan 32
SE- 431 35 Mölndal
Sweden

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.
Expiry date on MDR certificate is set to be aligned with client´s audit cycle for ISO 13485:2016 certificate.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2023-658566	Mölndal	Daniel Malica	11 – 12 Oct 2023
Stage 2 ACTY-2023-122550	Mölndal	Daniel Malica, Mikael Hagelin, Sofia Pavesio	28 – 30 Nov 2023

Technical Documentation Report	Assessor Name	Assessment Date
F104-1-4-MED-TDAR_Neoventa_TD00356-01_2024-01-12	Vinay Bhat	15 January 2024
F103-4-5-MED-CEAR_Neoventa_TD00356-01_2024-01-12	Vinay Bhat	15 January 2024
TD Request for Additional Information Neoventa___TD00356-01_2024-01-12	Vinay Bhat	15 January 2024
F210-1-MED_Request_for_Follow-up_During_Audit_Activity_2024-01-12	Vinay Bhat	15 January 2024

Scope of assessment

Non-active instruments, Class IIa

Result

2 minor non conformitiy were noted during the audit. Presented corrective action plans have been examined and approved by us.

All non-conformities noted during the technical documentation assessment(s) have been closed.

Certificate Type

EU Quality Assurance Certificate

Certificate Valid from

24 January 2024

Conclusions/Decisions

Referring to the above, a Certificate of Conformance with the Medical Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up assessments

Follow-up assessments are going to be performed once per year.

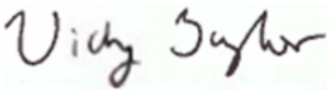
Appeals

Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR



Victoria Taylor
Certification Authority (TD Assessment)

Brian Mather
Certification Authority (Audit)

PRODUCT LIST FOR CERTIFICATE

Issued to: Neoventa Medical AB

Certificate number: 28620165315

Certificate valid from: 2024-01-24

Product List Issue Date:
24 January 2024

Product	Classification and EMDN	Intended use[1]	Date Added
Non-active instruments			
Basic UDI-DI: 73401549FSEV8			
CNS000004 - Goldtrace Fetal Spiral Electrode (FSE)	Class IIa V9099		2024-01-24

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB, Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.