EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

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

The Notified Body of TÜV NORD Scandinavia Medical Notified Body AB certifies that the manufacturer

Cetro Medical AB
Nitgatan 11
333 33 Smålandsstenar
Sweden

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of 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 conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. For devices of class IIb and IIa 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.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

Single Registration Number of the Manufacturer (SRN):	SE-MF-000012172
Authorised Representative:	see Section 1
Limitations and Conditions:	see Section 2
List of Products, Risk Classification and Details:	see Section 3
Certificate History:	see Section 4

Certificate number: CERT-000130

Valid from: 2026-04-20
Valid until: 2030-09-14
First issued: 2025-09-15
Issue date: 2026-04-20
Version: 3

Maria Eklycke

TÜV NORD Scandinavia Medical Notified Body AB is a Notified Body with identification number 3033

TÜV NORD Scandinavia Medical Notified Body AB
Isafjordsgatan 22, 164 40 Kista, Sweden
+46 10- 474 92 00
scandinaviamnb@tuv-nord.com
www. tuv-nord.com/scandinaviamnb

EU Quality Management System Certificate

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Annex IX, Chapters I and III
Certificate number: CERT-000130

Section 1, Authorised Representative

Company name:	N/A
Street, No.:	--
Postal Code, City:	--
Country:	--

Section 2, Limitations and Conditions

The validity of this Certificate depends on:	N/A
and the following conditions:	None
and / or is limited to the following:	N/A

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Section 3, List of Products, Risk Classification and Details

Device Group	Basic UDI-DI	Risk class	Intended purpose*
MDN 1202 Non-active devices for administration, channeling and removal of substances	73401943415SCM	IIa	N/A
MDN 1208 Non-active instruments	73401943961SE5	IIa	N/A
Class I device in sterile condition (EtO)	7340194342ASDT, 73401943120SBN, 73401943139SCN, 73401943967SEP, 73401943110SBH	Is	N/A

For class Is devices placed on the market in a sterile condition, the involvement of the notified body in the conformity assessment procedure is limited to those aspects related to the manufacture, securing and maintenance of sterile conditions.

* Only specified in EU certificate for class IIb devices

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Section 4, Certificate History

Issue	Date	Activity
1	2025-09-15	Original certificate
2	2025-10-20	Change of scope, removal of Basic UDI-DI 73401943962SE8 (MDN 1208)
3	2026-04-20	Change of scope, removal of Basic UDI-DI 734019431600A6 and 734019431650AM class Im devices. Change of name from RISE Medical Notified Body AB to TÜV NORD Scandinavia Medical Notified Body AB.

(Information on examinations and test per Annex XII, section 10 is available on request at scandinaviamnb@tuv-nord.com)

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The signatures in this document are legally binding. The document is signed using Penneo™ secure digital signature. The identity of the signers has been recorded, and are listed below.

"By my signature I confirm all dates and content in this document."

Maria Eklycke
On behalf of TNSC MNB
Serial number: 1f90eb5690da31[…]b9a2746346c08
IP: 83.233.xxx.xxx
2026-04-20 13:01:45 UTC