EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

Cert no. CERT-000130

Manufacturer: Cetro Medical AB

Adress:
Nitgatan 11
333 33 Smålandsstenar
Sweden

Single Registration Number (SRN): SE-MF-000012172

Attached:
Scope of device(s), page 2.

Regarding the requirements of the quality management system of the manufacturer in accordance with **Regulation (EU) 2017/745, Annex IX chapter I and III**, the quality systems meet the requirements. The quality management system is subject to periodical surveillance by RISE Medical Notified Body AB. The quality management system audits were accompanied by assessment of technical documentation for devices selected on a representative basis according to section 4, Annex IX.

For class Is devices, the audit by the notified body of the quality management system is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For class Im devices, the audit by the notified body of the quality management system is limited to the aspects relating to the conformity of the devices with the metrological requirements.

Originally issued	2025-09-15
Decision date	2025-10-20
Expiry date	2030-09-14

Issued by RISE Medical Notified Body AB, Notified Body Number 3033

Maria Eklycke

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Decision Maker

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Cert no. CERT-000130
Issue no. 2

Scope of device(s):

Device group	Basic UDI-DI	Risk class	Intended purpose[1]
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
Class I device with a measuring function	734019431600A6, 734019431650AM	Im	N/A

Conditions or limitations to the validity of the certificate:

No conditions or limitations.

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)

(Information on examinations and test per Annex XII, section 10 is available on request at mnb@ri.se)

[1] Only specified in EU certificate for class IIb devices

Verification

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Document

EU Certificate Annex IX Chapter I and III
Main document
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Signed 2025-10-20 15:53:27 CEST (+0200)