EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 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 restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements - has been carried out following the requirements of EU Regulation 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.

Sensidose

Vetenskapsvägen 10, Sollentuna, SE -191 38 Sweden

Manufacturer SRN: SE-MF-000005074

Scope:

Metrology aspects of devices as detailed in attached product list.

Certificate Number:
28620156249

Revision:
00

Initial Certification Date:
1 September 2023

Date of Certification Decision:
1 September 2023

Certificate Issue Date:
1 September 2023

Certificate Expiry Date:
31 August 2028

Mikael Hagelin
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

Last Audit report reference	**Stage 1 audit ACTY-2022-592913**
	Stage 2 audit ACTY-2022-592914
	Special Visit audit ACTY-2023-085430

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620156249

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MDR – Decision Report

Certificate No: 28620156249
Date: 1 September 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Sensidose AB
Attn: Maria Wikström
Vetenskapsvägen 10
SE-191 38 Sollentuna
Sweden

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2022-592913	Sollentuna Sweden	Helen Attmarsson Rydén	28 – 30 March 2023
Stage 2 ACTY-2022-592914	Sollentuna Sweden	Helen Attmarsson Rydén	22 – 25 May 2023
Special Visit ACTY-2023-085430	Remote	Helen Attmarsson Rydén	18 Aug 2023

Scope of assessment

Metrology aspects of devices as detailed in attached product list, Class I(m)

Result

1 major and 1 minor non conformity were noted during the audit. The major non conformity was successfully closed out at the special visit. Presented corrective action plan for the minor non conformity has been examined and approved by us.

Certificate Valid from

1 September 2023

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.

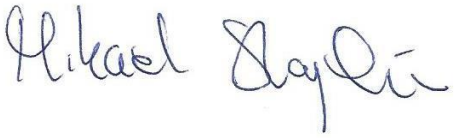
Appeals

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



Mikael Hagelin
Certification Authority

PRODUCT LIST FOR CERTIFICATE

Issued to: Sensidose AB

Certificate number: 28620156249

Certificate valid from: 2023-09-01

Product List Issue Date:
1 September 2023

Product	Classification and EMDN	Intended use[1]	Date Added
Class I devices with a measuring function			
Basic UDI-DI: 735007101SM-1000QZ			
SM-1000 - MyFID®	Class I(m)		2023-09-01

Mikael Hagelin
Certification Authority, MDR
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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.