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 sterility and 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.

Certificate Number:
28620147504

Revision:
00

Initial Certification Date:
20 April 2023

Date of Certification Decision:
20 April 2023

Certificate Issue Date:
20 April 2023

Certificate Expiry Date:
19 April 2028

SMB Corporation of India

Unit I : 13,33-36 Prem Industrial Estate, Subhash Road, Jogeshwari (E), Mumbai ,Maharashtra, 400 060, India

Manufacturer SRN: IN-MF-000023742

Authorised Representative Name

Obelis S.A.

Boulevard General Wahis 53, 1030 Brussels, Belgium,

Scope:

- Sterility aspects of devices as detailed in attached product list
- Metrology aspects of devices as detailed in attached product list

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

Last Audit report reference	**Stage 1 audit ACTY-2022-579092**
	Stage 2 audit ACTY-2022-579096

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620147504

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