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

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28620147504

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MDR – Decision Report

Certificate No: 28620147504
Date: 20 April 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

SMB Corporation of India
Attn: Mr. ANUPAM RAI
Unit I : 13,33-36 Prem Industrial Estate,
Subhash Road, Jogeshwari (E),
Mumbai ,Maharashtra, 400 060,
India

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-2022-579092	Mumbai, India	Parvinder Singh	7 – 9 Oct 2022
Stage 2 ACTY-2022-579096	Mumbai, India	Parvinder Singh	19 – 29 Dec 2022

Scope of assessment

Product category, Class

Result

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

Certificate Valid from

20 April 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

Brian Mather
Certification Authority

PRODUCT LIST FOR CERTIFICATE

Issued to: SMB Corporation of India

Certificate number: 28620147504

Certificate valid from: 2023-04-20

Product List Issue Date:
20 April 2023

Product	Classification and EMDN	Intended use[1]	Date Added
Class I sterile devices			
Basic UDI-DI: 890602860IUDCFG8			
CF - Clean Forceps	Class I(s) U0899		2023-04-20
Basic UDI-DI: 890602860IUDIRHJ			
ITR - IUD Thread Retriever	Class I(s) V9012		2023-04-20
Basic UDI-DI: 890602860IUDKCHK8			
CRF - Cheron Forceps	Class I(s) U0899		2023-04-20
Basic UDI-DI: 890602860IUDKKC			
IUDKT - IUD Kit Pack	Class I(s) V901699		2023-04-20
Basic UDI-DI: 890602860IUDKPTM7			
PZT - Pozzi Tenaculum	Class I(s) U0899		2023-04-20
Basic UDI-DI: 890602860IUDKSHS			
TCS - IUD Thread Cutting Scissor	Class I(s) V0199		2023-04-20
Basic UDI-DI: 890602860SMBSPKQ			
SP - Speculum	Class I(s) U089006		2023-04-20
Class I sterile devices with a measuring function			
Basic UDI-DI: 890602860SMBProbeUK			
DSP - Probe/Hysterometer	Class I(s,m) U089003		2023-04-20
PC - Probe/Hysterometer	Class I(s,m) U089003		2023-04-20
SSP - Probe/Hysterometer	Class I(s,m) U089003		2023-04-20

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

Product	Classification and EMDN	Intended use[1]	Date Added

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

Certificate number: 28620147504
Product list issue date: 20 April 2023

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by the referenced certificate

Subcontractor	Service Supplied
SMB Corporation of India Plot No. 156, GIDC Umbergaon, Dist. Valsad 396170, Gujarat, India	Manufacturing of devices Quality Control Storage of Raw material and finished devices

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