

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.

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

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



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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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			
<i>Basic UDI-DI: 890602860IUDCFG8</i>			
CF - Clean Forceps	Class I(s) U0899		2023-04-20
<i>Basic UDI-DI: 890602860IUDIRHJ</i>			
ITR - IUD Thread Retriever	Class I(s) V9012		2023-04-20
<i>Basic UDI-DI: 890602860IUDKCHK8</i>			
CRF - Cheron Forceps	Class I(s) U0899		2023-04-20
<i>Basic UDI-DI: 890602860IUDKKC</i>			
IUDKT - IUD Kit Pack	Class I(s) V901699		2023-04-20
<i>Basic UDI-DI: 890602860IUDKPTM7</i>			
PZT - Pozzi Tenaculum	Class I(s) U0899		2023-04-20
<i>Basic UDI-DI: 890602860IUDKSHS</i>			
TCS - IUD Thread Cutting Scissor	Class I(s) V0199		2023-04-20
<i>Basic UDI-DI: 890602860SMBSPKQ</i>			
SP - Speculum	Class I(s) U089006		2023-04-20
Class I sterile devices with a measuring function			
<i>Basic UDI-DI: 890602860SMBProbeUK</i>			
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

¹The 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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Brian Mather

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Certificate number: 28620147504

Product list issue date: 20 April 2023

