

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
216849-2017-AQ-IND-NA-PS

Initial certification date:  
13 April 2005

Valid:  
08 January 2022 – 07 January 2025

This is to certify that the management system of  
**SMB Corporation of India**  
13, 33-36, Prem Industrial Estate, Subhash Road, Jogeshwari (E), Mumbai - 400 060,  
Maharashtra, India  
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:  
**ISO 13485:2016 / EN ISO 13485:2016**

This certificate is valid for the following scope:

**Unit I : Design, Manufacturing and supply of sterile intra-uterine contraceptive devices, sterile or nonsterile non-absorbable sutures, Tubal Rings, Design and supply of Hypodermic Syringe with or without Needle , Design and manufacture of sterile and nonsterile insertion tube, solid rod, hystrometer/ probe, IUD thread retriever, and loading device, Forcep, Pozzi Tenaculum, Scissor and Speculum.**

**Unit II : Manufacturing and supply of sterile intra-uterine contraceptive devices, sterile or nonsterile non-absorbable sutures, Hypodermic Syringe with or without Needle, Tubal Rings, The manufacture of sterile and nonsterile insertion tube, solid rod, hystrometer/ probe, IUD thread retriever, and loading device, Forceps, Pozzi Tenaculum, Scissor and Speculum.**

Place and date:  
Høvik, 09 December 2021



For the issuing office:  
**DNV Product Assurance AS**  
Veritasveien 3, 1363 Høvik, Norway

*Cecilie Gudesen Torp*

**Cecilie Gudesen Torp**  
Management Representative

## Appendix to Certificate

### SMB Corporation of India

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
SMB Corporation of India	13, 33-36, Prem Industrial Estate, Subhash Road, Jogeshwari (E), Mumbai - 400 060, Maharashtra, India	Design, Manufacturing and supply of sterile intra-uterine contraceptive devices, sterile or nonsterile non-absorbable sutures, Tubal Rings, Design and supply of Hypodermic Syringe with or without Needle , Design and manufacture of sterile and nonsterile insertion tube, solid rod, hystrometer/ probe, IUD thread retriever, and loading device, Forcep, Pozzi Tenaculum, Scissor and Speculum
SMB Corporation of India	Plot No. 156, GIDC, Umbergaon, Valsad - 396170, Gujarat, India	Manufacturing and supply of sterile intra-uterine contraceptive devices, sterile or nonsterile non-absorbable sutures, Hypodermic Syringe with or without Needle, Tubal Rings, The manufacture of sterile and nonsterile insertion tube, solid rod, hystrometer/ probe, IUD thread retriever, and loading device, Forceps, Pozzi Tenaculum, Scissor and Speculum