

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

SMB Medical Devices Pvt. Ltd. (Doing business as SMB Corporation of India)

Main Site: Unit I : 13,34-36 Prem Industrial estate Subhash Road
Jogeshwari (E), Mumbai, Maharashtra, 400 060, India (FIN F005166)

Additional Site: 156 GIDC Umbergaon, Dist. Valsad, Gujarat 396170, India (FIN
F005167)

has been registered by Intertek, an MDSAP recognized auditing organization,
as conforming to the requirements of:

ISO 13485:2016

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA
n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

*Design and Manufacturing of sterile intra-uterine contraceptive devices,
sterile insertion tube, solid rod, hystrometer/ probe, IUD thread retriever,
and loading device, Forceps, Pozzi Tenaculum, Scissor and Speculum.*

Additional Site: Manufacturing, inspection, warehouse

Certificate Number:

0110410

Initial Certification Date:

2021-02-09

Certification Effective Date:

2021-02-09

Certification Expiry Date:

2024-02-08



Intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

