

# 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:**

2023-02-08



**Intertek**

**Calin Moldovean**

President, Business Assurance

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