

## Certificate of Registration of Quality Management System to ISO 13485: 2016

The National Standards Authority of Ireland certifies that: **Smooth Bor Plastics** 23322 Del Lago Drive Laguna Hills, CA 92653

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

Design, Manufacture and Distribution of flexible plastic tubing for medical device applications.

Additional sites covered under this multi-site certification are listed on the Annex (File No. CM19.4560)

Approved by: Geraldine Larkin Chief Executive Officer

**USA** 

Com Banville
Operations Manager,
Medical Devices

**Medical Devices** 

Certificate Number: CM19.4560 Certification Granted: Nov 26, 2013 Effective Date: Sep 18, 2018 Expiry Date: Sep 17, 2021





**Annex to Certificate Number: CM19.4560** 

## **Scope of Registration:**

Design, Manufacture and Distribution of flexible plastic tubing for medical device applications.

Activity	Location
Administration, Design, Manufacture	Smooth Bor Plastics 23322 Del Lago Drive Laguna Hills, CA 92653 USA File No.: CM19.4560
Distribution	Smooth Bor Plastics 19571 Pauling Foothill Ranch, CA 92610 USA File No.: CM19.4560/B
Manufacture, Distribution	Smooth Bor Plastics No 8, Jalan i-Park SAC 2 Taman Perindustrian i-Park SAC 81400 Senai, Johor Malaysia File No.: CM19.4560/C

Verified by:
Operations Man

**Operations Manager**