



NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Smooth Bor Plastics
23322 Del Lago Drive
Laguna Hills, CA 92653
USA

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. MD19.4560)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Registration Number: MD19.4560
Certification Granted: November 26, 2013
Effective Date: October 02, 2019
Expiry Date: September 17, 2021





NSAI

Annex to Certificate Number: MD19.4560

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.: MD19.4560

Distribution

Smooth Bor Plastics
15 Doppler
Irvine, CA 92618
USA
File No.: MD19.4560/B

Manufacture, Distribution

Smooth Bor Plastics
No 8, Jalan i-Park SAC 2
Taman Perindustrian i-Park SAC
81400 Senai, Johor
Malaysia
File No.: MD19.4560/C

**Verified by:
Operations Manager**