

# 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:

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**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:  
Kevin Mullaney  
Director of Certification

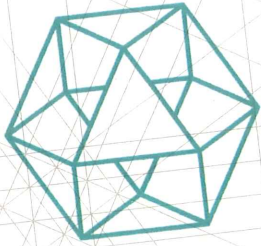
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Registration Number: MD19.4560  
Certification Granted: November 26, 2013  
Effective Date: September 18, 2024  
Expiry Date: September 17, 2027



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National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412



# 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 and Distribution of  
Components

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

Shipping, Receiving, Warehouse

Smooth Bor Plastics  
No. 15, Jalan i-Park SAC,  
Taman Perindustrian i-Park SAC  
81400 Senai, Johor  
Malaysia  
File No.: MD19.4560/D

**Verified by:  
Director of Certification**