



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Foamtec International Co., Ltd.

Laem Chabang Industrial Estate,

259 Moo 3, Toongsukla, Sri Racha, Chonburi

20230 Thailand

Holds Certificate Number: MD 719992

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture of foam support for medical devices.

Gary C Stade

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-03-02 Effective Date: 2020-03-02 Latest Revision Date: 2020-03-02 Expiry Date: 2023-03-01







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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated online.

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Further darifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.





## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: FOAMTEC INTERNATIONAL CO., LTD.

259/1, 259/2 and 259/3 Moo 3, Laemchabang Industrial Estate, Export Processing, Toongsukhla,

Sriracha, Chonburi

20230 Thailand

Holds Certificate Number: MD 731871

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture of applicators, pads, sterile and non-sterile swabs, sterile and non-sterile wipers, sterile foam dressing, and foam components, plastic assemblies for use as, or a component of an active, non-active or in-vitro diagnostic medical device.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-07-13 Effective Date: 2023-11-16 Latest Revision Date: 2024-12-10 Expiry Date: 2026-11-15

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## Location Registered Activities

FOAMTEC INTERNATIONAL CO., LTD. 259/1, 259/2 and 259/3 Moo 3, Laemchabang Industrial Estate, Export Processing, Toongsukhla, Sriracha, Chonburi 20230 Thailand The manufacture of applicators, pads, sterile and non-sterile swabs, sterile and non-sterile wipers, sterile foam dressing, and foam components, plastic assemblies for use as, or a component of an active, non-active or in-vitro diagnostic medical device.

FOAMTEC INTERNATIONAL CO., LTD 111/1 MOO 2, KM 56 of Phahonyothin Road, Lamsai, Wangnoi, Pranakornsriayutthaya 13170 Thailand Distribution of applicators, pads, sterile and non-sterile swabs, sterile and non-sterile wipers, sterile foam dressing, and foam components, plastic assemblies for use as, or a component of an active, non-active or in-vitro diagnostic medical device.



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