



Certificate of Registration

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

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

259 Moo3, Laemchabang Industrial Estate Export Processing Zone1,

Toongsukhla, Sriracha, Chonburi Province

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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-03-02 Effective Date: 2023-03-02 Latest Revision Date: 2023-02-08 Expiry Date: 2026-03-01



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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.

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +66(2) 2944889-92.

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

Shracha, Cho

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.

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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