

Certificate of Registration

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

This is to certify that:

Foamtec International Co., Ltd.
700/50, 52, 54 Moo 6
Amata City Chonburi Industrial Estate,
57 K.M. of Bangna-Trad Road,
T. Nongmaidang, A. Muangchonburi,
Chonburi
20000
Thailand

Holds Certificate Number:

MD 781568

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 sub-assembly non-sterile foam, film, rubber, sponge and adhesive components for medical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-01-13

Latest Revision Date: 2025-10-10

Effective Date: 2026-01-13

Expiry Date: 2029-01-12

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