

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 744453 R000

Manufacturer: FOAMTEC INTERNATIONAL CO., LTD

Address:

259/1 and 259/2 Moo 3
Laemchabang Industrial
Estate
Export Processing Zone
Toongsukhla, Sriracha
Chonburi
20230
Thailand

Single Registration Number: TH-MF-000017561

EU Authorised Representative: Obelis Group

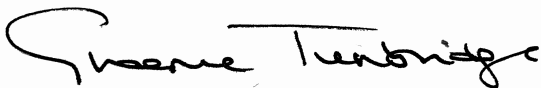
Address:

Boulevard Général Wahis 53
1030 Brussels
Belgium

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2021-04-14**

Date: **2022-08-24**

Expiry Date: **2026-04-13**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile CleanWIPE® Small Tip Foam Swab	Class Is
Sterile CleanWIPE® Medium Tip Foam Swab	Class Is
Sterile CleanWIPE® Medium Flexible Tip Foam Swab	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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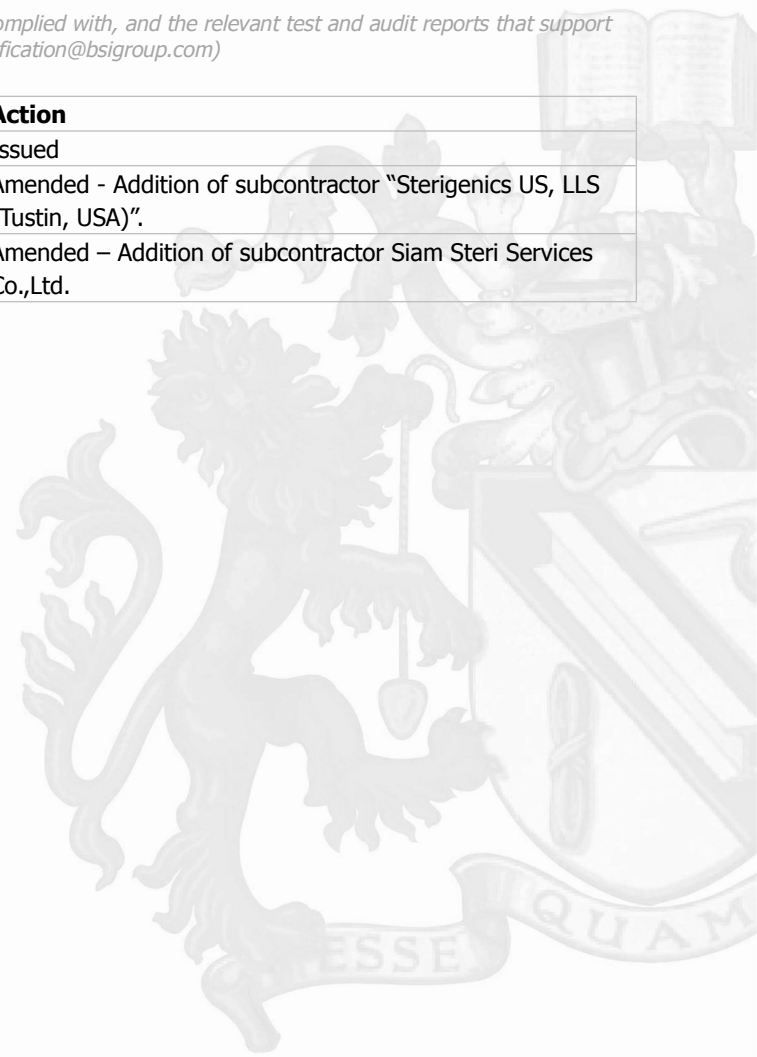
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-04-14	3388414	Issued
2022-04-07	3635612	Amended - Addition of subcontractor "Sterigenics US, LLS (Tustin, USA)".
Current	3718876	Amended – Addition of subcontractor Siam Steri Services Co.,Ltd.



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 744453 R000

Date: 2022-08-24

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Siam Steri Services Co.,Ltd. 700/644 Moo 3, Tambol Bankao, Amphur Panthong, Chonburi 20160 Thailand	ETO Sterilization
Sterigenics (Thailand) Ltd 109/16 Eastern Seaboard Industrial (Rayong) Moo 4 T. Pluakdaeng A. Pluakdaeng Rayong 21140 Thailand	Gamma Irradiation
Sterigenics US, LLC 1401 Morgan Circle Tustin California 92780 USA	Gamma Irradiation
Steris Tomoe (Thailand) Ltd 700/644 Moo 3 Tambon Bankao Amphur Panthong Chonburi 20160 Thailand	Gamma Irradiation

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 744453 R000

Date: 2022-08-24

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Synergy Health (Thailand) Ltd 700/465 Amata Nakorn Industrial Moo 7 Tambon Donhuaroh Amphur Muang Chonburi Chonburi 20000 Thailand	Gamma Irradiation



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