

# 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:** Not Available

**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):



Gary E Slack, Senior Vice President Medical Devices

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

Date: **2021-04-14**

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

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

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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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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.

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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
Current	3388414	Issued



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

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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: **2021-04-14**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Sterigenics (Thailand) Ltd 109/16 Eastern Seaboard Industrial (Rayong) Moo 4 T. Pluakdaeng A. Pluakdaeng Rayong 21140 Thailand	<b>Gamma Irradiation</b>
Steris Tomoe (Thailand) Ltd 700/644 Moo 3 Tambon Bankao Amphur Panthong Chonburi 20160 Thailand	<b>Gamma Irradiation</b>
Synergy Health (Thailand) Ltd 700/465 Amata Nakorn Industrial Moo 7 Tambon Donhuaroh Amphur Muang Chonburi Chonburi 20000 Thailand	<b>Gamma Irradiation</b>

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