

EU Quality Assurance Certificate

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

MDR 744453 R001

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

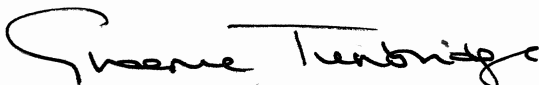
Address:

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 Global Regulatory & Quality

First Issue Date: **2021-04-14**

Current Issue Date: **2026-03-13**

Starting Validity Date: **2026-04-14**

Expiry Date: **2031-04-13**

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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.

EU Quality Assurance Certificate

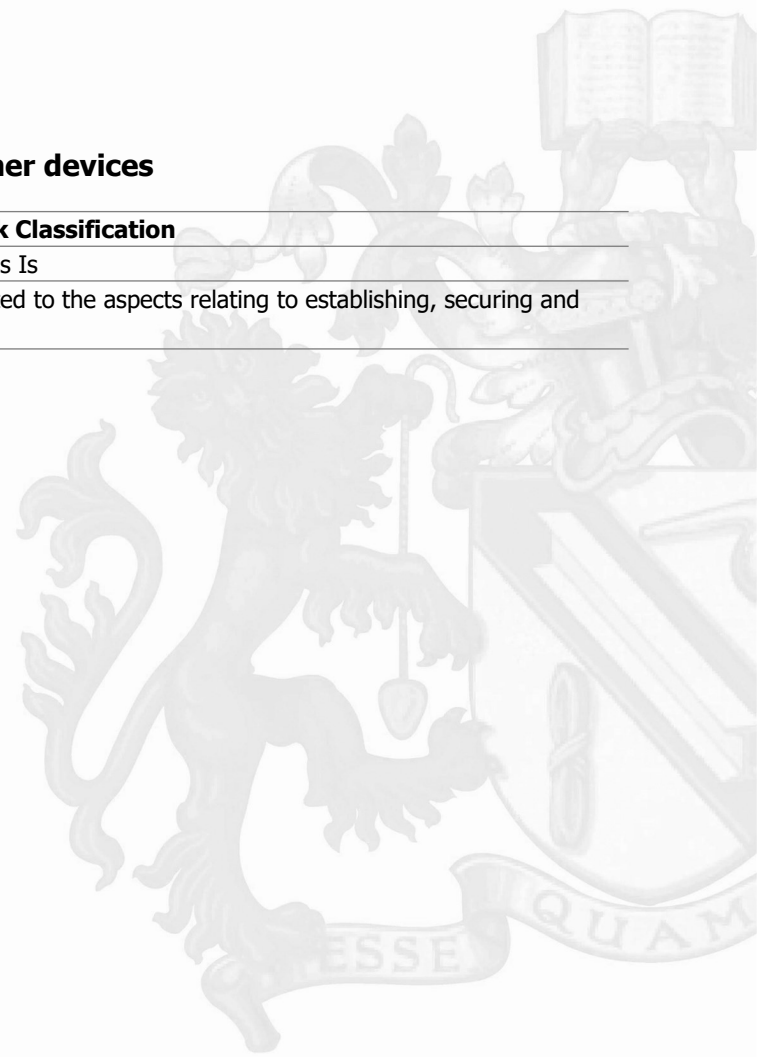
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile Foam Swabs	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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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)”.
2022-08-24	3718876	Amended – Addition of subcontractor Siam Steri Services Co.,Ltd.
Current	30490584	Re-Issued – Certificate Renewal. Amended – Change of scope wording to Sterile Foam Swabs.



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