

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

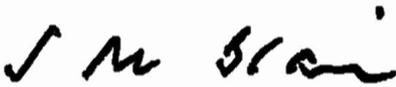
No. CE 632526
Issued To: **Getinge Sterilization AB**
Ekebergsvägen 26
Getinge
SE-30575
Sweden

In respect of:

Design, development, manufacture of sterilizers and autoclaves.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2015-06-05**

Date: **2019-01-16**

Expiry Date: **2024-01-15**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 632526

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIb		
38671	HS44*	Necessary accessory to reusable non-invasive and invasive medical items
38671	HS55*	
38671	GSS67H	
38671	HS714*	
40583	GSS67F	
Class IIa		
11278	GED1112*	-
11278	GED1118*	-

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Getinge IC Production Poland Sp. z o. o. Ul. Szkolna 30 Plewiska 62-064 Poland	Design Manufacture

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Certificate History

Certificate No: **CE 632526**
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Date	Reference Number	Action
05 June 2015	8295252	Initial Issue traceable to previous notified body certificate number 41310376
11 July 2016	8546295	Addition of in-scope device GSS67F. Removal of devices SM06.06* and SM09.06*. Change of address from Ekebergsvagen 26 to Ekebergsvägen 26.
Current	9699794	Renewal. Removal of devices HS66*, HS66*T, HS66*LTSF, HS66T*LTSF, HS69*, HS816*, HS914*, HS918*, HS1014*. Addition of subcontractor Getinge IC Production Poland Sp. z o. o. ul., Szkolna 30, Plewiska, 62-064, Poland

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