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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 632526

Issued To:

Getinge Sterilization AB
Ekebergsvägen 26
Getinge
SE-30575
Sweden

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*	

Digitally signed by Moldoveanu Ruxanda
Date: 2019.07.05 16:56:27 EEST
Reason: MoldSign Signature
Location: Moldova

First Issued: **2015-06-05** Date: **2019-01-16** Expiry Date: **2024-01-15**

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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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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 632526**

Date: **2019-01-16**

Issued To: **Getinge Sterilization AB**
Ekebergsvägen 26
Getinge
SE-30575
Sweden

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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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 632526**

Date: **2019-01-16**

Issued To: **Getinge Sterilization AB**
Ekebergsvägen 26
Getinge
SE-30575
Sweden

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 of Registration

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

This is to certify that:

Getinge Sterilization AB
Ekebergsvagen 26
Getinge
SE-30575
Sweden

Holds Certificate Number: MD 632508

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development and production of equipment and accessories for sterilization and disinfection.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-03-12
Latest Revision Date: 2018-05-18

Effective Date: 2018-05-27
Expiry Date: 2021-05-26

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MDD – Product List

Products included in the certificate no: 41314824
Issued to: **Getinge Disinfection AB**
Ljungadalsgatan 11
Box 1505
SE-351 15 Växjö
Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Washer Disinfector	Getinge 46-series, 46-2, 46-3, 46-4, 46-5	IIb	No	17671	*[1]
	Getinge 46-series, 46-4T, 46-5T	IIb	No	17671	Sep 15, 2010
	Getinge 88-Series, 88-5	IIb	No	17671	*[1]
	Getinge 8666, S-8666	IIb	No	17671	*[1]
	Getinge 8668, S-8668	IIb	No	17671	*[1]
	Getinge 9000-Series, 9027	IIa	No	17671	*
	Getinge 9100-Series, 9120, 9122, 9125, 9128	IIb	No	17671	*[1]
	Getinge CM320, CM320	IIb	No	17671	Feb 1, 2011
	Getinge WD 14 Tablo, GE14	IIb	No	17671	Nov 12, 2009[1]
	Getinge WD 15 Claro, GE15	IIb	No	17671	Aug 18, 2009[1]
Washer Disinfectors for human waste containers	Getinge FD 1600, Ninjo, FD 1600, FD 1605, FD 1610, FD 1615	IIa	No	35318	May 31, 2011
	Getinge FD 1800, Tornado, FD 1800, FD 1810	IIa	No	35318	May 31, 2011
	Getinge 607, 608, Amigo, S-607, S-608	IIa	No	35318	*
	Getinge 2000, Tornado, SP-1000	IIa	No	35318	*
	Getinge 1200, Ninjo, Ecomat, SP-1200	IIa	No	35318	*
	Getinge 6000, Typhoon, SP-6000	IIa	No	35318	*

* Product added before August 18, 2009.
[1] Product class change from IIa to IIb on 21 March 2010

Date of Issue: May 31, 2011

Intertek Semko AB
Notified Body MDD

Marie Olsson
Certification Manager MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00 , Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41314824

Initial Certification Date
November 1, 2004

Certificate Valid from
August 18, 2009

Certificate Expiry Date
August 18, 2014

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Getinge Disinfection AB

Ljungadalsgatan 11, Box 1505, 351 15 Växjö, Sweden

Product Category:

- Washer Disinfectors

For further identification of the products covered, see the MDD product list/product schedule.

August 18, 2009
Signed date

Marie Olsson, Certification Manager MDD
Intertek Semko AB, Kista, Sweden