



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			
38671	HS55*	invasive medical items			
38671	GSS67H				
38671	HS714*				
40583	GSS67F				
Class IIa					
11278	GED1112*	**			
11278	GED1118*				

First Issued: 2015-06-05

Date: 2019-01-16

Expiry Date: 2024-01-15

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wholey of this pertificate is constituted in the quality system forms maintained to the requirements of the Directive as demonstrated through the required surveillance artificials of the pipilland Body. This accuracy is children in this certificate, which specifically agreed with 851.

This complicate was assued electronically and is bound by the conditions of the contract

immirrachii and Contact, BSI, Albemark Court, Dars Allettur, Kriovelliel, Nutron Keynes MKS 899, Tell. + 44-245 080-9000 BSI Assistance UK Limited, registered in England under number 2605321 at 289 Chiswick High Read, London WR 481, UK. Almentier of SSI Group of Companies.





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

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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Page 1 of 2

Validity of this certificate is conditional on the quality system being in attained to the requirements of the Directive as demonstrated through the required survivales as the Notified Both. This approval excludes all products designed and/or manufactured by a third party on behalf of the company contract this conditate, unless specificate agreed with BSL.

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowinil, Milton Keynes MKS 8PP. Tel: + 44-345 0ag 9000. BSI Assurance UK Limited, registered in England under number 7895321 at 389 Chiewick High Road, London W4-4AL, UK, A member of BSI Group of Companies.

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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	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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Validity of the critificate is conditional on the quality system being traintained to the requirements of the Directive as demonstrated through the required surveivance and vities of the Northed Body. This approval excludes as products designed and/or manufactured by a third party on behalf of the company. This certificate, unless specificate, and is bound by the conditions of the contract.

Information and Contact ISST, Kitemark Court, Davy Avenue, Knowlfill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 ISSI Assurance UK Limited, registered in England under number 7805321 at 389 Christnek High Road, London W4 4AL, UK. A member of EST Group of Companies.

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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

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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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract or electronic certificate can be authenticated online.

Finited copies can be validated at www.bsigroup.com Vm/ClicatDirector



MDD - Product List

Products included in the certificate no:

Issued to:

41314824

Getinge Disinfection AB

Ljungadalsgatan 11

Box 1505

SE-351 15 Växjö

Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code	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	llb	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	lla	No	17671	*
	Getinge 9100-Series, 9120, 9122, 9125, 9128	Ilb	No	17671	*1
	Getinge CM320, CM320	Ilb	No	17671	Feb 1, 2011
	Getinge WD 14 Tablo, GE14	llb	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	lla	No	35318	May 31, 2011
	Getinge FD 1800, Tornado, FD 1800, FD 1810	lla	No	35318	May 31, 2011
	Getinge 607, 608, Amigo, S-607, S-608	lla	No	35318	*
	Getinge 2000, Tornado, SP-1000	lla	No	35318	*:
	Getinge 1200, Ninjo, Ecomat, SP-1200	lla	No	35318	*
	Getinge 6000, Typhoon, SP-6000	lla	No	35318	

^{*} Product added before August 18, 2009.

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.

Product list for certificate no: 41314824 Date: May 31, 2011

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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



¹ Product class change from IIa to IIb on 21 March 2010



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 Rody.

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

Inlertek 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