



EC Certificate - Full Quality Assurance System

Supplementary Information to CE 632526

Issued To:

First Issued: 2015-06-05

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*				

R. Mui Date: 2019-01-16

Expiry Date: 2024-01-15

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which, of this certificate is communal in the quality system from maintained to the requirements of the Directive as demonstrated through the required surveillance actuative. Of the Frontied Booy. This expression actually and the designed and/or manufactured by a third party on behalf of the company named on this certificate, where shell control is bound by the conditions of the control.

Information and Contact: BSI, Albomark Court, Date: A legion, Knowibilit, Milton Keynes MRS SPP, Tell. + 44-345-080-0000 BSI Assenance UK Limited: registered in England under number 1805521 at 289 Chiewick High Read, London W4-44L, UK A member of SSI Group of Companies.





EC Certificate - Full Quality Assurance System

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

No. Issued To:

CE 632526 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



Expiry Date: 2024-01-15

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Values of this certificate is conditional on the quality system being in Sinfacined to the requirements of the Directive as demonstrated through the required sub-silication with the Nearfield Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company control on this certificate, unless specificate agreed with BSL.

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

Information and Contact: BST, Kitemark Court, Davy Avenue, Knowihill, Mitton Keynes MK5 8PP. Tel: + 44 345 089 9000 BST Assurance UK Limited, registered in England under number 7805321 at 389 Chiewick High Road, London W4 4AL, UK, A member of BST Group of Companies.





EC Certificate - Full Quality Assurance System Certificate History

Certificate No: Date: Issued To: CE 632526 2019-01-16 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	July 2016 8546295 Addition of in-scope device GSS67F. Removal of of 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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values of the intrificate is combanal on the quality system heing the name to the requirements of the Directive as demonstrated through the required surveivance intrificate is found work. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this cartificate, unless specificatis agreed with BS1. This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BST, Kitemark Court, Devy Avenue, Knowihill, Milton Keynes MKS 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AI, UK. A member of ESI Group of Companies.





EC Certificate - Full Quality Assurance System By Royal Charter

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: Date: Issued To:

2019-01-16 **Getinge Sterilization AB** Ekebergsvägen 26 Getinge SE-30575 Sweden

CE 632526

Subcontractor:

Getinge IC Production Poland Sp. z o. o. Ul. Szkolna 30 Plewiska 62-064 Poland

Service(s) supplied

Design Manufacture



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MKS 8PP. Tel: + 44 345 080 9000 ESI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.





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 with the requirements of ISO 13485 with the requirements of ISO 13485 with the requirements of ISO 13485 with the requirements of

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



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For and on behalf of BSI:

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

UKA

Stewart Brain, Head of Compliance & Risk - Medical Devices

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

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This certificate was issued electronically and remains the property of BSE and is bound by the conditions of contract. An electronic certificate can be authenticated **online.** Printed copies can be validated at www.begroup.com/ClientDirectory.

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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 çode (not mendatory)	Date added
Washer Disinfector	Getinge 46-series, 46-2, 46-3, 46-4, 46-5	llb	No	17671	*1
	Getinge 46-series, 46-4T, 46-5T	llb	No	17671	Sep 15, 2010
	Getinge 88-Series, 88-5	llb	No	17671	*1
	Getinge 8666, S-8666	llb	No	17671	*1
	Getinge 8668, S-8668	llb	No	17671	*1
	Getinge 9000-Series, 9027	lla	No	17671	*
	Getinge 9100-Series, 9120, 9122, 9125, 9128	llb	No	17671	*1
	Getinge CM320, CM320	llb	No	17671	Feb 1, 2011
	Getinge WD 14 Tablo, GE14	llb	No	17671	Nov 12, 2009 ¹
	Getinge WD 15 Claro, GE15	llb	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	8

* Product added before August 18, 2009

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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.

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



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.

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

21 EXUSTANT