

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 19, 2014

Certificate Expiry Date
August 18, 2019

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, LVFS 2003:11, 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.

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
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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.

July 25, 2014

Signed date



Mats Premfors, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

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 <small>(not mandatory)</small>	Date added
Washer Disinfector	Getinge 46-series, 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, FD 1805	IIa	No	35318	May 31, 2011 May 28, 2014
	Getinge, S-607, S-608, Amigo	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

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Intertek Semko AB
 Notified Body MDD



Mats Premfors
 Certification Authority 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.

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Product list for certificate no: 41314824
 Date: August 19, 2014
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