

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41311788

Initial Certification Date
July 9, 1998

Certificate Issue Date
July 9, 2013

Certificate Expiry Date
July 9, 2018

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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Telephone +46 8 750 00 00
medtechsweden@intertek.com*

Organization:

Getinge Skärhamn AB

Industrivägen 5, SE - 471 31 Skärhamn, Sweden


Product Category:

- Sterilizers for medical devices

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

June 27, 2013

Signed date


Hans Ericsson, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

Products included in the Certificate No: 41311788

Issued to:

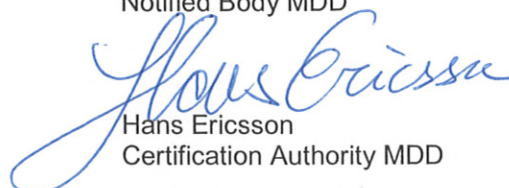
Getinge Skärhamn AB
Industrivägen 5
SE- 471 31 Skärhamn
Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Autoclave 60 and 100 litres	HS33 601197804xxxx xxxx stands for user interface version; single automatic door or double automatic door or single manual door	IIb	No	-	*
Autoclave 10, 15 and 20 litres	K-Series 97804xxxx xxxx stands for chamber volume; white cover or stainless steel cover	IIb	No	-	*
Autoclave 18 litres	Quadro 97804950x x stands for user interface version	IIb	No	-	Oct 26, 2011

* Product added before March 30, 2010.

Date of Issue: June 27, 2013

Intertek Semko AB
Notified Body MDD


Hans Ericsson
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: 41311788

Date: June 27, 2013

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