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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

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

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.

Organization:

Andersen Sterilizers, Inc.

Main Site: 3154 Caroline Drive, Health Science Park, Haw River, NC 27258, USA

Product Category:

- Ethylene Oxide Gas Sterilizers including Cartridge Kit

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

Certificate Number:
41314704-02

Initial Certification Date:
27 April 2004

Certificate Valid from:
28 April 2019

Certificate Expiry Date:
27 April 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

26 April 2019
Signed Date

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

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.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request

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MDD – Product List

Products included in the Certificate No: 41314704-02
Issued to: **Andersen Sterilizers, Inc.**
3154 Caroline Drive
Health Science Park
Haw River, NC 27258, USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Sterilizers	AN306	IIb	No		*
	AN310	IIb	No		*
	AN333	IIb	No		*
	AN74I	IIb	No		*
	AN74IX	IIb	No		*
	AN74J	IIb	No		*
	AN75	IIb	No		30 Jan 2020
	AN2000	IIb	No		*
	AN4000	IIb	No		*
Cartridge Kits	AN1004	IIb	No		*
	AN1005	IIb	No		*
	AN1006	IIb	No		*
	AN2011	IIb	No		*
	AN2014	IIb	No		*
	AN2018	IIb	No		*
	AN71	IIb	No		*
	AN73	IIb	No		*
	AN7514	IIb	No		30 Jan 2020
	AN7916	IIb	No		*

* Product added before March 21, 2010.

Date of Issue: 30 January 2020

Intertek Semko AB
Notified Body MDD

Peter Nermander
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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MDD – Product Decision

Certificate No: 41314704-02
Date: January 30, 2020
Handled by: Beverley Oakley
E-mail: medtechsweden@intertek.com

Andersen Sterilzers, Inc.
Attn: Kayla Kerschus
Health Science Park
3154 Caroline Drive,
Haw River, NC 27258-9575
USA

Purpose

Assessment of the notification dated November 11, 2019 for addition of new products toyour quality system certified according to LVFS 2003:11, Annex II (Swedish implementation of MDD 93/42/EEC).

Products concerned

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)
Sterilizers	AN75	IIb	No	
Cartridge Kits	AN7514	IIb	No	

Conclusions/Decisions

The products are similar to previously accepted products.

The application has been accepted and the products can be added.

Application of the CE-mark is permitted when the company's own procedures for CE-marking are fulfilled.

Follow-up assessments

At the next audit your auditor may follow-up on the implementation of the new products in the Quality system.

Appeals

Any appeal against this decision will be processed by an appeals panel at Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD