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EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system - restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions - has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

CHANGZHOU DSB MEDICAL CO., LTD

Main Site: #98, Fumin Road, Qishuyan Economic Development Zone, Qishuyan District, Changzhou City, Jiangsu Province, China

Product Category:

- Class I sterile devices

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

* Previously certified by Intertek AMTAC (NB0473) to date 02 July 2018

Certificate Number:
41377404-01

Initial Certification Date:
14 July 2014*

Certificate Valid from:
14 July 2019

Certificate Expiry Date:
27 May 2024

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

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

25 June 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.

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MDD – Product List

Products included in the certificate no: 41377404-01
Issued to: **CHANGZHOU DSB MEDICAL CO., LTD**
#98, Fumin Road, Qishuyan Economic Development Zone, Qishuyan District, Changzhou City, Jiangsu Province, China

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Class I sterile devices					
	Equipment Cover	I(s)	Yes	-	02 July 2018
	Adult Urine bag	I(s)	Yes	-	02 July 2018
	Pediatric Urinary collection bag	I(s)	Yes	-	02 July 2018

Date of Issue: 25 June 2019

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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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.intertek.se
Registered in Sweden: No SE556024059901, Registered office: As address