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 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:

A C Cossor & Son (Surgical) Ltd

Main Site: Greig House, Block 1 Annickbank Innovation Campus, Annick Road, Irvine, KA11 4LF, United Kingdom

Product Category:

- Pressure infusion cuffs
- Electronic Blood pressure measuring instruments
- Aneroid blood pressure measuring instruments

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

*Previously certified by Intertek AMTAC (NB0473) to date 22 January 2018

Certificate Number:
41371237-03

Initial Certification Date:
22 January 2018*

Certificate Valid from:
19 August 2020

Certificate Expiry Date:
26 May 2024

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

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

19 August 2020
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.

MDD – Product List

Products included in the certificate no: 41371237-03

Issued to: **A C Cossor & Son (Surgical) Ltd**
Greig House, Block 1
Annickbank Innovation Campus, Annick Road,
Irvine, KA11 4LF,
United Kingdom

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Electronic blood pressure measuring instruments					
	Greenlight 300	IIa	No	16174	Jan 22, 2018
Aneroid blood pressure measuring instruments					
	Accoson Duplex sphygmomanometer	I(m)	No	16156	Jan 22, 2018
	Accoson Limpet sphygmomanometer	I(m)	No	16156	Jan 22, 2018
	Accoson Pocket sphygmomanometer	I(m)	No	16156	Jan 22, 2018
	Accoson Combine sphygmomanometer	I(m)	No	16156	Jan 22, 2018
	Accoson 6” Aneroid sphygmomanometer	I(m)	No	16156	Jan 22, 2018
	Accoson SIX00 series Aneroid sphygmomanometer	I(m)	No	16156	Jan 22, 2018
	Accoson Blood Pressure Cuffs, bulb valves and component parts	I(m)	No	16156	Jan 22, 2018
Pressure infusion cuffs					
	Pressure Infusion Cuff	I(m)	No	13100	Jan 22, 2018

Date of Issue: 19 August 2020

Intertek Semko AB
Notified Body MDD

Bob Andersson
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.

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

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MDD – Decision Report

Certificate No: 41371237-03
Date: 19 August2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

A C Cossor & Son (Surgical) Ltd
Attn: Hugh Templeton
Greig House Block 1 Annickbank Innovation Campus
Annick Road, Irvine KA11 4LF
United Kingdom

Purpose	Assessment to issue a new EC Certificate due to five year extension and address change. The old address was Cumberland House, Drake Avenue, Staines-Upon-Thames, Middlesex, TW18 2AW, United Kingdom Decision was made according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V.
Activity	Certification audit was performed 21 January 2020 in Irvine by Helen Attmarsson Rydén. The technical file was reviewed 19 August 2020 by Steve Ward at Intertek's office.
Scope of assessment	- Pressure infusion cuffs - Electronic Blood pressure measuring instruments - Aneroid blood pressure measuring instruments Class I(m), Class IIa
Result	5 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us
Certificate Valid from	19 August 2020
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.

Appeals

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

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority MDD