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:

Hammarplast Medical AB

Main Site: Kartåsgatan 8, 531 40 Lidköping, Sweden

Product Category:

- Disposables, Class I Sterile
- Medicine measures, disposables, Class I Measuring

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

Certificate Number:
41319092-05

Initial Certification Date:
19 January 2011

Certificate Valid from:
20 January 2021

Certificate Expiry Date:
26 May 2024

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

Mikael Hagelin
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

8 January 2021
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: 41319092-05

Issued to: **Hammarplast Medical AB**
Kartåsgatan 8
SE- 531 40 Lidköping
Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Disposables, Class I sterile	Hpm Disposable Tourniquet cuff (1 chamber/line) Size (cm) 20x5 Size (inch) 8x2 Art no 15-100	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (1 chamber/line) Size (cm) 30x 8 Size (inch) 12x3 Art no 15-110	I	Yes	-	Sep 19, 2014
	Hpm Disposable Touniquet cuff (1 chamber/line) Size (cm) 38x10 Size (inch) 15 x 4 Ref nr 15-120	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (1 chamber/line) Size (cm)46x10 Size (inch) 18 x 4 Ref nr 15-130	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (1 chamber/line) Size (cm) 61x10 Size (inch 24 x 4) Ref nr 15-140	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (1 chamber/line) Size (cm) 76 x13 Size (inch) 30 x 5,1 Ref nr 15-150	I	Yes	-	Sep 19, 2014

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Registered in Sweden: No SE556024059901, Registered office: As address

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Hpm Disposable Tourniquet cuff (1 chamber/line) Size (cm) 86 x 13 Size (inch) 34 x 5,1 Ref nr 15-160	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (1 chamber/line) Size (cm) 97 x 13 Size (inch) 38 x 5,1 Ref nr 15-170	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (1 chamber/line) Size (cm) 109 x 13 Size (inch) 43 x 5,1 Ref nr 15-180	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (2 chamber/line) Size (cm) 25 x10 Size (inch)10 x 4 Ref nr 25-100	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (2 chamber/line) Size (cm) 36 x10 Size (inch) 14 x 4 Ref nr 25-110	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (2 chamber/line) Size (cm) 51 x 15 Size (inch) 20 x 6 Ref nr 25-120	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (2 chamber/line) Size (cm) 66 x 15 Size (inch) 26 x 6 Ref nr 25-140	I	Yes	-	Sep 19, 2014

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Hpm Disposable Tourniquet cuff (2 chamber/line) Size (cm) 81 x 15 Size (inch) 32 x 6 Ref nr 25-160	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (conical 1 chamber/line) Size (cm) 61 x10 Size (inch) 24 x 4 Ref nr 75-140	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (conical 1 chamber/line) Size (cm) 76 x 10 Size (inch) 30 x 4,1 Ref nr 75-150	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (conical 1 chamber/line) Size (cm) 86 x 11 Size (inch) 34 x 4, 3 Ref nr 75-160	I	Yes	-	Sep 19, 2014
	Hpm Disposable Tourniquet cuff (conical 1 chamber/line) Size (cm) 109 x 13 Size (inch) 43 x 5 Ref nr 75-170	I	Yes	-	Sep 19, 2014

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MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Medicine measures, disposables, Class I measuring	Narrow medicine measure (nature, yellow, blue, red, and green) 30ml, 5ml grade 01250-01254 J10823-J10833	I(m)	No		*
	Wide medicine measure (nature, yellow, blue, red, and green) 30ml, 5 ml grade 10300-10304	I(m)	No		*
	Eco medicine measure (nature,yellow,blue, red and green) 30ml 01350-01354	I(m)	No		Nov 13, 2015
	Eco+ medicine measure (nature, yellow, blue, red and green) 30ml 02250-02254	I(m)	No		Feb 04, 2019

* Product added before September 22, 2009.

Sign Date: 8 January 2021
Valid Date: 20 January 2021

Intertek Semko AB
Notified Body MDD

Mikael Hagelin
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 – Decision Report

Certificate No: 41319092-05
Date: 8 January 2021
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Hammarplast Medical AB
Attn: Ann-Charlotte Johansson
Kartåsgatan 8
SE- 531 40 Lidköping
Sweden

Purpose	Assessment to issue a new certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V.
Activity	Certification audit was performed 8 October 2020 in Lidköping by Gabriel Johansson.
Scope of assessment	- Medicine cup, Class I measuring - Disposables, Class I Sterile
Result	3 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	20 January 2021
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

Mikael Hagelin
Certification Authority MDD