Hpm™

Declaration of Conformity

Council Directive 93/42/EEC

Manufacturer:
Hammarplast Medical AB
Kartåsgatan 8
531 40 Lidköping
Sweden

Hammarplast Medical AB declares that devices listed on the attached MDD product lists no 41319092 from Intertek Semko and Certificate of registration no 6.6.1-2013-95170 from Swedish MPA meets the requirements of the Swedish legislation 1993:584 and LVFS 2003:11 and conform to the relevant provisions of the EC Council Directive 93/42/EEC.

This declaration is supported by the quality system certification based on the harmonized standard SS-EN ISO 13485:2012

Lidköping 2014-04-24

Ann-Charlotte Johansson
QA/RA manager

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Total Quality. Assured.

MDD – Product List

Products included in the Certificate No: 41319092-02
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
Pneumatic Tourniquet	Electronic Tourniquet *models* 800-20 800-40	IIa	No		Mar 26, 2012
	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

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 – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	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
	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

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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) 66 x 15 Size (inch) 26 x 6 Ref nr 25-140	I	Yes	-	Sep 19, 2014
	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.

Date of issue: February 04, 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.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

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