



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

Hammarplast Medical AB
Kartåsgatan 8, 531 40 Lidköping, Sweden Tel +46-510-618 80
Västberga Allé 36 B, 126 30 Hägersten, Sweden Tel +46-510-618 80

Corporate no: 556108-9284

Products included in the Certificate No: 41319092-01

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
Manual surgical saw, flexible	Scandmed Gigli Wire Saw <i>in the following sizes (30-40 is the size in mm)</i>	Ila	No		Mar 01, 2012
	110-30				
	110-40				
	110-50				
Pneumatic Tourniquet	Electronic Tourniquet models 800-20 800-40	Ila	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 Tourniquet 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

Product List for Certificate No: 41319092-01

Date: January 20, 2016

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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

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

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

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	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
Medicine measures, disposables, Class I measuring	Narrow medicine measure (nature, yellow, blue, red, and green) 30ml, 5ml grade 01250-01254 J10823-J10833	I measuring function	No		*
	Wide medicine measure (nature, yellow, blue, red, and green) 40ml, 5 ml grade 10300-10304	I measuring function	No		*
	Eco medicine measure 01350-01354	I measuring function	No		Nov 13, 2015

* Product added before September 22, 2009.

Valid from: January 20, 2016

Signed date: December 18, 2015

Intertek Semko AB
Notified Body MDD



Mats Premfors
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.

Product List for Certificate No: 41319092-01

Date: January 20, 2016

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Torshamnsgatan 43, Box 1103, SE-184 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