Intertek

EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41316788-02

Initial Certification Date
June 25, 2009

Certificate Valid from
June 26, 2014

Certificate Expiry Date
June 25, 2019

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.

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

We hereby declare that an examination of the under mentioned full 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 II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

MedXL Inc.

285, rue Labrosse, Pointe-Claire, QC H9R 1A3, Canada

Product Category:

Prefilled Syinge for maintaining patency of Vascular Access Devices (VADs)

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

May 23, 2014
Signed date

Mats Premfors, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2008-09-01

MDD – Product List

Products included in the Certificate No: 41316788-02
Issued to: **MedXL**
285, rue Labrosse
Pointe-Claire, QC H9R 1A3
Canada

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Sodium Citrate 4% Prefilled Syringe	CitraFlow 2,5ml / Ref: 385425E1	IIa	Yes	-	June 25, 2009
	CitraFlow 2,5ml x 2 / Ref: 385425-1E1	IIa	Yes	-	June 25, 2009
	Citra Flow 3ml in 5cc syringe / Ref: 38543	IIa	Yes	-	Jan 17, 2014
	CitraFlow 3ml in 5cc syringe x 2 / Ref: 38543-1	IIa	Yes	-	Jan 17, 2014
	Citra Flow 3ml in 10cc syringe / Ref: 38553	IIa	Yes	-	Jan 17, 2014
	CitraFlow 5ml in 10cc syringe / Ref: 38555	IIa	Yes	-	Jan 17, 2014
	CitraFlow 5ml / Ref: 3854E1	IIa	Yes	-	June 25, 2009
Sodium Citrate 30% Prefilled Syringe	CitraFlow™ 3ml in 5cc syringe / Ref:38243	IIa	Yes	-	May 23, 2014
	CitraFlow™ 3ml in 5cc syringe x 2 / Ref:38243-1	IIa	Yes	-	May 23, 2014
Sodium Citrate 46.7% Prefilled Syringe	CitraFlow™ 3ml in 5cc syringe / Ref:38143	IIa	Yes	-	May 23, 2014
	CitraFlow™ 3ml in 5cc syringe x 2 / Ref:38143-1	IIa	Yes	-	May 23, 2014
0.9% Sodium Chloride Prefilled Syringe	Praxiject™ 5ml in 5cc syringe / Ref:3704	IIb	Yes	-	Oct 25, 2013
	Praxiject™ 3ml in 5cc syringe / Ref:37043	IIb	Yes	-	Oct 25, 2013
	Praxiject™ 3ml in 10cc syringe / Ref:37053	IIb	Yes	-	Oct 25, 2013
	Praxiject™ 5ml in 10cc syringe / Ref:37055	IIb	Yes	-	Oct 25, 2013
	Praxiject™ 10 ml in 10cc / Ref:3705C	IIb	Yes	-	Oct 25, 2013
	Praxiject™ 20 ml in 20cc / Ref:3706	IIb	Yes	-	Jan 23, 2015

Intertek Semko AB
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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Product List

Date of Issue: January 20, 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.

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