Intertek

EC Certificate

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

Certificate Number
41315667

Initial Certification Date
April 25, 2007

Certificate Valid from
April 25, 2012

Certificate Expiry Date
April 25, 2017

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 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:

Iradimed Corp.

7457 Aloma Avenue, Winter Park, FL 32792, USA

Product Category:

- Infusion Systems for MRI and General Purpose Use
- Infusion Sets
- Patient Monitors and accessories

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

April 19, 2012
Signed date

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

2008-09-01

MDD – Decision Report

Certificate No: 41315667
Date: April 19, 2012
Handled by: Erika Jureskog
E-mail: medtechsweden@intertek.com

Iradimed Corp
Fran Casey
7457 Aloma Avenue
Winter Park, FL 32792
USA

Purpose	Five year extension assessment according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Yearly surveillance audits have been performed during the past five year period. The most recent audit was performed April 5-6, 2012 in Winter Park, FL by George Mason. No non conformities were noted during the audit.
Scope of assessment	- Infusions Systems for MRI and General Purpose Use - Infusion Sets - Patient Monitors and accessories Class IIa and IIb
Issue date of certificate	April 25, 2012
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 II has been extended. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Yearly follow-up assessments are going to be performed.
Appeals	Any appeal shall be submitted to the manager of Medical Regulatory Services, Intertek Semko AB, 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

Mats Premfors
Certification Manager MDD

MDD – Product List

Products included in the certificate no: 41315667
Issued to: **Iradimed Corp.**
7457 Aloma Avenue
Winter Park, FL 32792
USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Infusions Systems					
MRidium 3850 Infusion System	MRidium 3850 MRI IV Pump	IIb	No		*
	Wireless IV Pump Remote Control / 3855	IIb	No		*
	Side Car, modular second pump channel / 3851	IIb	No		*
MRidium 3860 Infusion System (with or without Pulse Oximeter)	MRidium 3860 MRI IV Pump	IIb	No		July 2, 2009
	Wireless IV Pump Remote Control / 3865	IIb	No		July 2, 2009
	Side Car, modular second pump channel/ 3861	IIb	No		July 2, 2009
Infusion Sets					
MRidium 1000 Series Infusion Sets	Bypass Infusion Set / 1055	IIa	Yes		*
	Standard Infusion Set / 1056	IIa	Yes		*
	Syringe Adapter Infusion Set / 1057	IIa	Yes		*
	Standard Extension Set / 1058	IIa	Yes		April 19, 2012

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.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Patient Monitoring Systems					
iMagox 2460 Pulse Oximeter System	iMagox 2460 MRI Pulse Oximeter	IIb	No		April 19, 2012
	Wireless Pulse Oximeter Remote Control / 2465	IIb	No		April 19, 2012

* Product added before April 19, 2012.

Signed Date: April 19, 2012
Valid from: April 25, 2012

Intertek Semko AB
Notified Body MDD

Mats Premfors
Certification Manager 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.

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.sweden.intertek-etlsemko.com
Registered In Sweden: No SE556024059901, Registered office: As address