

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41313861

Initial Certification Date
May 26, 2008

Certificate Issue Date
May 26, 2008

Certificate Expiry Date
May 26, 2013

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
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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:

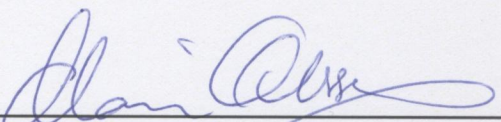
Diagnosys LLC

175 Cabot Street, Suite 500, Lowell, MA 01854, USA

Product Category:

Electrophysiology equipment for vision testing

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


Marie Olsson, Certification Manager MDD
Intertek Semko AB, Kista, Sweden

Products included in the certificate no: 41313861
 Issued to: Diagnosys LLC
 175 Cabot Street, Suite 500
 Lowell, MA 01854
 USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)
E2 Espion Console	D215	Ila	-	
ColorDome Desktop Ganzfeld Stimulator	D125	Ila	-	
ColorBurst Hand-held Stimulator	D213	Ila	-	
PSG Pattern Stimulator	D173	Ila	-	
FSG Pattern Stimulator	D217	Ila	-	
GoldLens Electrode	D101, D102	Ila	-	
DTL Plus Fiber Electrode	D141	Ila	-	
DTL Cable Extender	D144	Ila	-	
Espion Console	D212	Ila	-	
Power Block	D112		-	
MaculoScope	D130	Ila	-	
Dual ColorBurst Controller	D159	Ila	-	
Standalone Controller	D175	Ila	-	
Patient Headbox	D216	Ila	-	

Date of Issue: 26 May 2008

Intertek Semko AB
 Notified Body MDD



Marie Olsson
 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.

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Product list for certificate no: 41313861
 Date: 26 May 2008