

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

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

Certificate Number
41315757

Initial Certification Date
September 24, 2007

Certificate Issue Date
September 24, 2007

Certificate Expiry Date
September 24, 2012

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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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:

Innovative BioCeramix Inc.

1628 West 75th Avenue, Vancouver, BC V6P 6G2, Canada

Product Category:

Dental filling material

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: 41315757
 Issued to: Innovative BioCeramix Inc.
 1628 West 75th Avenue
 Vancouver, BC V6P 6G2
 Canada

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)
Dental Filling Material	BioA 4605-K6	Ila	-	
Root Canal Filling Material	iRoot SP	Ila	-	
	iRoor BP	Ila	-	

Date of Issue: January 28, 2009

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: 41315757
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