EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Integra York PA, Inc.

589 Davies Drive
York, PA 17402
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

endoscopes, endoscopic instruments, suction tubes and cannulas, bi- and monopolar RF/HF surgical instruments and electrodes, RF/HF accessories, surgical instruments, sterilization containers, tracheal and layryngectomy tubes, dental instruments, dental devices and dental material, ophthalmic devices, ligating devices and accessories, membrane tacks, ENT packing material
The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration No.	399673 MR2
Certificate unique ID	170583435
Effective date	2013-11-18
Expiry date	2018-11-17
Frankfurt am Main	2013-11-18

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

20120803/2/EN380308

Annex to Certificate
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Product:	Risk class:
Endoscopes	IIa
Endoscopic instruments	IIa
Suction tubes and cannulas	IIa
Bi- and monopolar RF/HF surgical instruments and electrodes	IIb
RF/HF accessories	IIb
Surgical instruments	Im, Is and IIa
Tracheal and layryngectomy tubes	IIa
Dental instruments	Im and IIa
Dental devices and dental material	IIa
Ophthalmic devices	Is
Ligating devices and accessories	IIa
Membrane tacks	IIb
ENT Packing Material	Is