

Declaration of Conformity

We, Integra York PA, Inc., located in York, Pennsylvania, USA declare under our sole responsibility that the products to which this declaration relates are in conformity with the following standard(s) or other normative document(s) where applicable.

Declaration Number: DC-YK-S002

Revision: 04

Product Identification: *Scissors (including Integra, Jarit, Miltex, Padgett, Padgett by Miltex and Ruggles)*

Catalog No: See Attached List

Conformity Assessment

Device Classification:	Route to Compliance:	Sterile/ Non Sterile	Standards Applied:
Class I Rules 1, 5 and 6	Annex VII of MDD 93/42/EEC Council Directive	Non Sterile	ISO 13485, CAN/CSA ISO 13485-03 ISO 14971, CAN/CSA ISO 14971-07 ASTM F 899 ISO 10993-1 EN ISO 15223-1 EN 1041 EN 62366-1 MDD 93/42/EEC MEDDEV 2.7.1 CMDR SOR/98-282 ISO 17664 ISO 17665 ISO 14937 ISO 11737-1 ISO 11737-2 EN ISO 15883-1 EN ISO 15883-2 AAMI TIR 12 AAMI TIR 30 ANSI/AAMI ST 46 ANSI/AAMI ST 79 ASTM F 1089-2 ISO 13402 ISO 7153-1

Manufacturer

Company Name:	Address:	Representative:
Integra York PA, Inc.	589 Davies Drive York, PA 17402 USA	Patricia Kihn

Authorized Representative

Company Name:	Address:	Telephone:
Integra LifeSciences Services	SAS Immeuble Sequoia 2 97 allée Alexandre Borodine Parc Technologique de la Porte des Alpes 69800 Saint Priest-France	Telephone: 33 (0) 4 37 47 5910 Fax: 33 (0) 4 37 47 5929

Integra York PA, Inc. declares that the above mentioned/attached products meet the provisions of the following:

- European Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EEC concerning medical devices
- ISO 13485:2003 Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes
- Harmonized Standards listed as per the current Essential Requirements Checklist

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All supporting documentation is maintained by the manufacturer.

Company Representative: Ruthanne Vendy, RAC
Sr Manager, Regulatory Affairs
Integra York, PA USA

Signature:



Date of Issue:

01/28/16

Place of Issue:

York PA, USA

This Declaration of Conformity is valid until: November 2018