RUMEX®
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Declaration of Conformity

We, Rumex International Co.,

14240 Carlson Circle, Building K,
Suit 8, Tampa, FL 33626, USA

declare on our own responsibility that the products:

Adapters	Curettes	Injectors	Scissors
Aspirators	Depressors	Knives	Scrapers
Blade holders	Dilators	Loops	Shields
Brushes	Dissectors	Mallets	Spatulas
Burrs	Electric Eye Cautery	Markers	Speculums
Calipers	Fixation Rings	Needles	Sponges
Cartridges	Forceps	Needle Holders	Spoons
Cannulas	Foreign Body Spuds	Prechoppers	Sterilization Trays
Chisels	Funnels	Probes	Trephines
Choppers	Gauges	Punches	Trocars
Clamps	Hooks	Retractors	Tubes
		Rongeurs	Vitrectomy Cutters

which are Reusable Surgical Manual instruments, with no measurement functions, sold non-sterile and to which this declaration relates is in conformity with the following stands or other normative documents:

EN ISO 14971:2012 Medical devices. Application of risk management to medical devices
ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.
EN 1041:2008 Information supplied by the manufacturer of medical devices
EN ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
EN 62366:2008 Medical devices -- Application of usability engineering to medical devices
ISO 13485:2016 Medical devices -- QMS -- Requirements for regulatory purposes

Mentioned above products meets all applicable provisions of the medical device directive

COUNCIL DIRECTIVE 93/42/EEC
Of 14 June 1998 concerning medical devices as amended by Directive 2007/47/EEC

Risk Classification

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EC REP

RUMEX BALTICS SIA
Robezu iela 46, Riga, LV-1004

In according to information above the CE Mark can be put on declared instruments on Rumex International Co. responsibility.

Inessa Cellentani
CEO
RUMEX INTERNATIONAL CO

RUMEX INTERNATIONAL CO CORPORATE SEAL 1994 FLORIDA

AFFORDABLE INNOVATIONS