

Declaration of Conformity

We, Rumex International Co.,
 13770 58th Street North,
 Suite 303
 Clearwater,
 FL. 33760 USA

declare on our own responsibility that the products:

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

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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Manufacturing site

Rumex instruments, Ltd.
 34 Sibirsky Tract, Buliding 4
 Kazan , Tatarstan
 420029 RUSSIAN FEDERATION



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

