

## Declaration of Conformity

We, Rumex International Co.,

14240 Carlson Circle, Building K,  
Suite 8, Tampa, FL 33626, 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

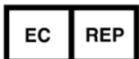
COUNCIL DIRECTIVE 93/42/EEC  
Of 14 June 1998 concerning medical devices as amended  
by Directive 2007/47/EEC

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

