DECLARATION OF CONFORMITY

The objects of the declaration is in conformity with the following relevant Union harmonization legislations:

Manufacturer:	**ELMI SIA** Bukultu street 7b, Riga LV-1005, Latvia Phone: (+371) 67558 743
Equipment name:	RM-2S, RM-2M, RM-2L, V-3
Equipment type:	Medical Intelli-Mixer, Medical Vortex-type mixer
Directives:	EMC Directive 2014/30/EU The low voltage directive (LVD) 2014/35/EU RoHS3 2015/863/EU Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment WEEE 2012/19/EU Directive on waste electrical and electronic equipment In-vitro Diagnostic Medical Devices Directive 2017/745
Class Risk:	the medical device has been asigned to class I according to Annex VIII of the Regulation 2017/745/EU
Applied standards:	EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use EMC requirements. General requirements. EN 61010-1:2011 Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements. EN 61010-2-051:2015 Particular requirements for laboratory equipment for mixing and stirring.

Intended use: laboratory devices that enable the mixing of diverse liquid samples.

Vitalijs Mironovs
Technical Director

09.09.2024
Date

Maksims Sviridovs
Manufacturing Director

09.09.2024
Date

ISO 13485 Certified