DECLARATION OF CONFORMITY

The undersigned ELMI SIA company declares that the following instrument(s) conforms the below mentioned directives and standards:

Manufacturer:	**ELMI SIA** Bukultu street 7b, Riga LV-1005, Latvia Phone: (+371) 67558 743
Equipment name:	CM-8S, CM-8, CM-50, CM-50M, CM-50MP, CM-7S Plus, CM-7S, CM-70M.07, CM-70M.09, CM-6M, CM-6MT
Equipment type:	Medical laboratory centrifuge
Serial number	8 digits styled XX Y ZZZZ T, where XX is year of production, Y — quarter of production, ZZZZ – batch number, T – device modification
Directives:	In-Vitro Diagnostic Medical Devices Directive 2017/745 EMC Directive 2014/30/EU Low Voltage Directive 2014/35/EU RoHS3 2015/863/EU WEEE 2012/19/EU
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 61010-2-020: 2016 Particular requirements for laboratory centrifuges.

Intended use: designed to separate solutions into fractions. Used in medicine, analytical chemistry, microbiology, serology, clinical biochemistry, etc.

ISO 13485 Certified

Vitalijs Mironovs
Technical Director

08.04.2024
Date

Maksims Sviridovs
Manufacturing Director

Digitally signed by Stoianova Elena
Date: 2025.09.19 06:52:48 EEST
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Location: Moldova
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08.04.2024
Date