



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
Phones: (+371) 67558 743, (+371) 67551 934

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, CM-70

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 assigned to class I according to Annex VIII of the Regulation 2017/745 EU

Applied standards:	<u>EN 61326-1: 2013</u> Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements. <u>EN 61010-1: 2011</u> Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements. <u>EN 61010-2-020: 2016</u> Particular requirements for laboratory centrifuges.
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Intended use: designed to separate solutions into fractions. Used in medicine, analytical chemistry, microbiology, serology, clinical biochemistry, etc.

Vitalijs Mironovs
Technical Director

Maksims Sviridovs
Manufacturing Director



08.04.2024
Date

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