

SLOVENSKI STANDARD oSIST prEN IEC 61010-2-020:2020

01-marec-2020

Varnostne zahteve za električno opremo za meritve, nadzor in laboratorijsko uporabo - 2-020. del: Posebne zahteve za laboratorijske centrifuge

Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges

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Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 2-020: Exigences particulières pour centrifugeuses de laboratoire

<u>oSIST prEN IEC 61010-2-020:2020</u> Ta slovenski standard je istoveten^cz:log/staprEN IEC 61010-2-020:2020 196472291c41/osist-pren-iec-61010-2-020-2020

ICS:

| 19.080 | Električno in elektronsko preskušanje | Elec testi |
|-----------|---|---------------|
| 71.040.10 | Kemijski laboratoriji. Laboratorijska oprema | Che Labo |

Electrical and electronic testing Chemical laboratories. Laboratory equipment

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66/711/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

| PROJECT NUMBER: | | |
|-----------------------|--------------------------|--|
| IEC 61010-2-020 ED4 | | |
| DATE OF CIRCULATION: | CLOSING DATE FOR VOTING: | |
| 2020-01-10 | 2020-04-03 | |
| SUPERSEDES DOCUMENTS: | | |
| 66/682/RR | | |

| IEC TC 66 : SAFETY OF MEASURING, CONTROL AND LABORATORY EQUIPMENT | | | | |
|--|--|--|--|--|
| SECRETARIAT: | SECRETARY: | | | |
| United Kingdom | Mr David Hyde | | | |
| OF INTEREST TO THE FOLLOWING COMMITTEES: | PROPOSED HORIZONTAL STANDARD: | | | |
| | | | | |
| | Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary. | | | |
| FUNCTIONS CONCERNED: | FUNCTIONS CONCERNED: | | | |
| | QUALITY ASSURANCE SAFETY | | | |
| Submitted for CENELEC parallel voting Standards.iten.al | | | | |
| Attention IEC-CENELEC parallel voting oSIST prEN IEC 61010-2-020:2020 | | | | |
| The attention of IEC National Committees, and and sist of ards/sist/c628face-cc1f-4fd0-a6ce- CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. ^{41/0} Sist-pref-icc-61010-2-020-2020 | | | | |
| The CENELEC members are invited to vote through the CENELEC online voting system. | | | | |

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Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-020: Particular requirements for laboratory centrifuges

PROPOSED STABILITY DATE: 2024

NOTE FROM TC/SC OFFICERS:

The revision is to align IEC 61010-2-020:2016 with IEC 61010-1:2010 and its amendment 1:2016. A revision this soon is justified by the large number of significant changes introduced by this amendment 1. With this revision IEC 61010-2-020 will be in line with the latest requirements of IEC 61010-1 + A1. Establishment of a new edition is for better readability instead of amending edition 3.

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| 21 | Ann | exes |
| 22 | Ann | ex L Index of defined terms. _{0515T prEN IEC 61010-2-020/2020} |
| 23 | Ann | ex AA (normative) Dynamic microbiological testimethod for BIOSEALS |
| 24 | Ann | ex BB (informative) General guidance and rationale for particular subclauses |
| 25 26 | | ex CC (informative) General guidance for an empirical method to determine the tic energy of a ROTOR |
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| 34 | | INTERNATIONAL ELECTROTECHNICAL COMMISSION |
|--|------|--|
| 35 | | |
| 36 37 38 | | SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE – |
| 39 40 | | Part 2-020: Particular requirements for LABORATORY CENTRIFUGES |
| 41 42 | | FOREWORD |
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| 76 77 | | ernational Standard IEC 61010-2-020 has been prepared by IEC technical committee 66: affety of measuring, control and laboratory equipment. |
| 78 79 | | is fourth edition cancels and replaces the third edition published in 2016. It constitutes a chnical revision and includes the following significant changes from the second edition: |
| 80 | a) | alignment with changes introduced by Amendment 1 of 61010-1 third edition. |
| 81 | lt l | has the status of a product safety publication in accordance with IEC Guide 104. |
| 82 | | |

83 The text of this standard is based on the following documents:

| CDV | Report on voting |
|---------------------------|----------------------------|
| 66/ <mark>542</mark> /CDV | 66/ <mark>565A</mark> /RVC |

84

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

This Part 2-020 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010) and its Amendment 1 (2016).

This Part 2-020 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Safety requirements for LABORATORY CENTRIFUGES*.

Where a particular subclause of Part 1 is not mentioned in this Part 2, that subclause applies as far as is reasonable. Where this part states "addition", "modification" or "replacement", the relevant requirement, test specification or note in Part 1 should be adapted accordingly.

- 96 In this standard:
- 1) the following print types are used:
- 98 requirements: in Toman Sype; ANDARD PREVIEW
- 99 NOTES: in small roman type; (standards.iteh.ai)
- 100 conformity and tests: in italic type;
- 101 terms used throughout this Standard which 2 have 0 been defined in Clause 3: SMALL
 102 ROMAN CAPITALIS://standards.iteh.ai/catalog/standards/sist/c628faec-cc1f-4fd0-a6ce-
- subclauses, tables or figures which are additional to those in Part 1 are numbered starting
 from 101; additional annexes are lettered AA, BB, etc.

A list of all parts of the IEC 61010 series, under the general title: *Safety requirements for electrical equipment for measurement, control, and laboratory use*, may be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- 111 reconfirmed,
- 112 withdrawn,
- replaced by a revised edition, or
- amended.
- 115
- 116

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR 117 MEASUREMENT, CONTROL, AND LABORATORY USE -118

119

Part 2-020: Particular requirements for laboratory centrifuges

120 121

122

123

Scope and object 1 124

- This clause of Part 1 is applicable except as follows: 125
- 1.1.1 Scope 126
- Replacement: 127
- This Part 2 is applicable to electrically powered LABORATORY CENTRIFUGES. 128

It is possible that all or part of the equipment falls within the scope of one or more 129 other Part 2 standards of IEC 61010 as well as within the scope of this standard . In that 130 case, the requirements of those other Part 2 standards will also apply 131

This document is not applicable to electrically powered LABORATORY CENTRIFUGES. 132 manufactured before the date of its publication. 133

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1.1.2 Equipment excluded from scope 134 standards.iteh.ai)

- Addition: 135
 - oSIST prEN IEC 61010-2-020:2020
- Add the following new item: https://standards.iteh.ai/catalog/standards/sist/c628faec-cc1f-4fd0-a6ce-136
- IEC 60034 (Rotating electrical machinery); aa) 137
- 1.2 Object 138
- 1.2.1 Aspects included in scope 139
- Addition: 140
- Add the following new items: 141
- contact with moving parts (see 7.3); 142 aa)
- LABORATORY CENTRIFUGE movement during any DISRUPTION (see 7.3.101): 143 bb)
- cc) high energy chemical reaction after ROTOR DISRUPTION (see 7.7.2.2 I)); 144
- ineffectiveness of BIOSEALS (see 13.101) dd) 145
- 146 1.2.2 Aspects excluded from scope
- Addition: 147
- Add the following new items: 148
- additional precautions which may need to be observed when centrifuging materials 149 aa) which are flammable or explosive (see 5.4.101); 150
- bb) additional precautions which may need to be observed when centrifuging materials that 151 could react chemically with sufficient vigour to cause a HAZARD (see 5.4.101). 152

| 153 | 1.4 | Environmental | conditions |
|-----|-----|---------------|------------|
| | | | |

- 154 **1.4.1 Normal environmental conditions**
- 155 Replacement:
- 156 Replace item c) by the following:
- 157 c) temperature 2 °C to 40 °C;
- 158 **1.4.2 Extended environmental conditions**
- 159 Replacement:
- 160 Replace item c) by the following:
- 161 c) ambient temperatures below 2 °C or above 40 °C;

162 2 Normative references

- 163 This clause of Part 1 is applicable except as follows:
- 164 Addition:
- 165 ISO 3864 (all parts), Graphical symbols Safety colours and safety signs

166 3 Terms and definitions

- (standards.iteh.ai)
- 167 This clause of Part 1 is applicable except as follows:

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- 168 **3.1 Equipment and states of equipment**/standards/sist/c628faec-cc1f-4fd0-a6ce-196472291c41/osist-pren-iec-61010-2-020-2020
- 169 Addition:
- 170 Add the following new terms and definitions:
- 171 **3.1.101**
- 172 LABORATORY CENTRIFUGE
- apparatus intended for laboratory use that applies a centrifuging effect to sample materials
- 174 **3.1.102**
- 175 CENTRIFUGE-ROTOR COMBINATION
- 176 LABORATORY CENTRIFUGE and ROTOR ASSEMBLY that are intended to operate together and which
- 177 have to be evaluated together
- 178 **3.1.103**
- 179 DISRUPTION
- 180 event in which the ROTOR ASSEMBLY, or part of it, fails or becomes detached during rotation
- 181

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7

3.2 Parts and accessories 182

- Addition: 183
- Add the following new terms and definitions: 184

3.2.101 185

- CHAMBER 186
- enclosed space within a LABORATORY CENTRIFUGE in which the ROTOR ASSEMBLY rotates 187
- 3.2.102188
- ROTOR 189
- primary component of a LABORATORY CENTRIFUGE which holds the material to be subjected to 190
- centrifugal force and which is rotated by the DRIVE SYSTEM 191
- 3.2.103 192
- BUCKET 193
- sub-assembly of a ROTOR designed to support one or more containers 194

3.2.104 195

PROTECTIVE CASING 196

casing which completely surrounds the ROTOR ASSEMBLY and which includes the LID and its 197 198 securing devices

3.2.105 199

- LID 200
- access cover of the CHAMBER 201

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3.2.106 202

203 ROTOR ASSEMBLY

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ROTOR carrying a combination of ROTOR accessories specified by the manufacturer

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205 Note 1 to entry: In the context of a ROTOR ASSEMBLY, ROTOR accessories include all components used with or in 206 the CENTRIFUGE ROTOR for the purpose of holding samples, including adaptors, tubes and bottles.

207 3.2.107

- DRIVE SYSTEM 208
- all components of the CENTRIFUGE associated with the provision of torque to, or the rotational 209 210 support of, the ROTOR ASSEMBLY

3.2.108 211

212 BIOSEAL

213 device or mechanism additional to, or integral with, a ROTOR or BUCKET and a closure assembly, and which is designed to prevent the escape of contents, for example micro-214 biological material, during centrifuging 215

3.5 Safety terms 216

- Addition: 217
- Add the following new terms and definitions: 218

219 3.5.101

- 220 **CLEARANCE ENVELOPE**
- space around a LABORATORY CENTRIFUGE which is needed for safety 221

222

| 2 |
|---|
| |

224 MCA

225 MAXIMUM CREDIBLE ACCIDENT

- planned event chosen to represent worst-case conditions for a test that will evaluate the inherent mechanical safety of a CENTRIFUGE-ROTOR COMBINATION (see 7.7 and Annex BB)
- 228 **4 Tests**
- 229 This clause of Part 1 is applicable.

5 Marking and documentation

This clause of Part 1 is applicable except as follows.

232 5.1.2 Identification

- 233 Replacement:
- Replace item b) by the following:
- b) serial number or other means to identify the production batch of the equipment.
- 236 Addition:

239

- 237 Add the following additionen STANDARD PREVIEW
- 238 5.1.3 Mains Supply

Addition: <u>oSIST prEN IEC 61010-2-020:2020</u> https://standards.iteh.ai/catalog/standards/sist/c628faec-cc1f-4fd0-a6ce-196472291c41/osist-pren-iec-61010-2-020-2020

240 Add the following note

NOTE - The maximum power or input current considered is usually during the acceleration phase of the rotor, with any options such as cooling or heating energized.

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243 Add the following new subclause:

244 **5.1.101** ROTORS and accessories

All OPERATOR-replaceable ROTORS and ROTOR ASSEMBLIES, including ROTOR ACCESSORIES, shall be marked with the manufacturer's or supplier's name or registered trade mark, and identification code. (such as id code, serial number or batch number)

If components are too small, or are not suitable for such marking, the required informationshall be marked on the original packaging, as well as being stated in the documentation.

250 NOTE Packaging can be the outer box, an insert, etc.

If the manufacturer specifies that an individual part, for example a BUCKET, is to be fitted only
 to a specific ROTOR or in specific ROTOR positions for balance or some other reason, each
 BUCKET and ROTOR position should be identified by marking with corresponding numbers or
 letters.

255 Conformity is checked by inspection.

256 **5.4.2 Equipment ratings**

257 Addition:

- Add the following new items:
- 259 aa) a list of all ROTORS and ROTOR accessories specified for use with a LABORATORY 260 CENTRIFUGE, together with their RATED rotational frequencies;
- 261 bb) any restrictions by the manufacturer warning against the use of particular materials to 262 be centrifuged;
- cc) density and volume limits for ROTOR ASSEMBLY loading and, if applicable, derating instructions.
- 265 **5.4.3 Equipment installation**
- 266 Addition:
- Add, after item a), the following sub-items:
- i) floor or bench area required for the CLEARANCE ENVELOPE for the intended use (see
 7.4.101);
- ii) total weight of the CENTRIFUGE;
- iii) instructions for site preparation;
- iv) methods for levelling of the CENTRIFUGE;
- v) means for securing to the mounting surface.
- 274 5.4.4 Equipment operation
- 275 Addition:

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- 276 Add the following new items: (standards.iteh.ai)
- 277 aa) loading and balancing procedures; <u>oSIST prEN IEC 61010-2-020:2020</u>
- cc) any specific requirement/for an/operator to the oppresent at stated phases of the centrifuging procedure;
- dd) necessary safeguards for personnel. Instructions shall include at least the following:
- 282 not to lean on a LABORATORY CENTRIFUGE;
- not to stay within the CLEARANCE ENVELOPE longer than necessary for operational
 reasons;
- 285 not to deposit any potentially hazardous materials within the CLEARANCE ENVELOPE;
- 286 methods for safe operation during open LID procedures (see 7.3.102.2);
- ee) instructions for use of BIOSEALS and other biocontainment components, including the proper closure techniques. These instructions shall indicate that BIOSEALS and related components are intended to be part of biocontainment systems, as specified in international and national biosafety guidelines. They are not to be relied on as the only means of safeguarding workers and the environment when handling pathogenic microorganisms.
- **5.4.5 Equipment maintenance and service**
- 294 Addition:
- Add the following new paragraph:
- 296 Where applicable, the instructions shall specify:
- aa) inspection of any means of fixing the equipment to the mounting surface and the
 condition of the mounting surface itself;
- 299 bb) safeguards for the OPERATOR during cleaning;

- 300 cc) inspection of the PROTECTIVE CASING;
- dd) inspection of the ROTOR ASSEMBLY, and safety considerations;
- 302 ee) checking the continuity of the PROTECTIVE BONDING;
- 303ff)frequency of inspection, routine maintenance and the method of replacement of304BIOSEALS and other biocontainment components.
- 305 Addition:

306 Add the following new subclauses:

307 5.4.101 Hazardous substances

The instructions for use shall state the precautions to be observed when the materials to be used with a LABORATORY CENTRIFUGE are known to be toxic, radioactive, or contaminated with pathogenic micro-organisms.

- 311 NOTE This information is relevant to the safety of both OPERATORS and service personnel.
- The use within the LABORATORY CENTRIFUGE of the following materials shall be prohibited in the instructions for use:
- a) flammable or explosive materials;
- b) materials which could react chemically with sufficient vigour to cause a HAZARD.
- 316 Conformity is checked by inspection.

5.4.102 Cleaning and decontamination

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- 318 Documentation shall include:
- a) a statement that, if hazardous material is split on or inside the equipment, the user has
 responsibility for carrying out appropriate decontamination;c1f-4fd0-acce-
- b) manufacturer's recommendations for cleaning and, where necessary, decontaminating, together with the recognized generic names of recommended materials for cleaning and decontaminating:
- 324 c) the following statement:
- "Before using any cleaning or decontamination methods except those recommended by
 the manufacturer, users should check with the manufacturer that the proposed method will
 not damage the equipment"
- 328 d) the following statement:
- Cleaning and decontamination may be necessary as a safeguard before LABORATORY CENTRIFUGES, ROTORS, and any accessories are maintained, repaired, or transferred. Manufacturers may provide a format for users to document that such treatment has been carried out
- NOTE Be advised, there are national guidelines and the internationally recognized "Laboratory Biosafety Manual",
 published in 1993 by the Wor5ld Health Organization in Geneva, which gives information on decontaminants, their
 use, dilutions, properties, and potential applications.
- 336 Conformity is checked by inspection.

5.4.103 Effects of chemicals and environmental influences

- To ensure continued safe use of a LABORATORY CENTRIFUGE the documentation shall identify damage which could result from, for example:
- a) the effect of chemicals;
- b) environmental influences, including natural ultra-violet radiation likely to be encountered;
- c) corrosion, and other weakening of construction materials that are part of the PROTECTIVE
 CASING or other protective components.