

**SLOVENSKI STANDARD**  
**oSIST prEN IEC 61010-2-040:2019**  
**01-december-2019**

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**Varnostne zahteve za električno opremo za meritve, nadzor in laboratorijsko uporabo - 2-040. del: Posebne zahteve za sterilizatorje in pralnike-dezinfektorje, ki se uporabljajo za obdelavo medicinskih materialov**

Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

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Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 2-040: Exigences particulières pour stérilisateurs et laveurs désinfecteurs utilisés pour traiter le matériel médical

**Ta slovenski standard je istoveten z: prEN IEC 61010-2-040:2019**

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**ICS:**

11.080.10	Sterilizacijska oprema	Sterilizing equipment
19.080	Električno in elektronsko preskušanje	Electrical and electronic testing
71.040.10	Kemijski laboratoriji. Laboratorijska oprema	Chemical laboratories. Laboratory equipment

**oSIST prEN IEC 61010-2-040:2019 en,fr,de**

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66/699/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:

IEC 61010-2-040 ED3

DATE OF CIRCULATION:

2019-10-04

CLOSING DATE FOR VOTING:

2019-12-27

SUPERSEDES DOCUMENTS:

66/696/RR

IEC TC 66 : SAFETY OF MEASURING, CONTROL AND LABORATORY EQUIPMENT	
SECRETARIAT: United Kingdom	SECRETARY: Mr David Hyde
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62D	PROPOSED HORIZONTAL STANDARD: <input type="checkbox"/> Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: <input type="checkbox"/> EMC <input type="checkbox"/> ENVIRONMENT <input type="checkbox"/> QUALITY ASSURANCE <input checked="" type="checkbox"/> SAFETY	
<input checked="" type="checkbox"/> SUBMITTED FOR CENELEC PARALLEL VOTING	<input type="checkbox"/> NOT SUBMITTED FOR CENELEC PARALLEL VOTING
<p><b>Attention IEC-CENELEC parallel voting</b>  <a href="https://standards.iteh.ai/catalog/standards/sist/35b4e019-19f4-4cc8-814b-300000000000/iec-61010-2-040-2020">https://standards.iteh.ai/catalog/standards/sist/35b4e019-19f4-4cc8-814b-300000000000/iec-61010-2-040-2020</a>            The attention of IEC National Committees members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.</p> <p>The CENELEC members are invited to vote through the CENELEC online voting system.</p>	

This document is still under study and subject to change. It should not be used for reference purposes.

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 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials**

PROPOSED STABILITY DATE: 2023

NOTE FROM TC/SC OFFICERS:

This CDV is intended only to align IEC 61010-2-040:2015 with IEC 61010-1:2010 and its amendment 1:2016 and provide minor editorial corrections. With this revision IEC 61010-2-040 will be in line with

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the latest requirements of IEC 61010-1 + A1.

This document contains no technical changes to already accepted base documents (IEC 61010-1:2010 and its amendment 1:2016 and IEC 61010-2-040:2015) but two;

1. Clause 6.8.3.1 is modified because otherwise it would need a specific European deviation in order to be harmonised to the LVD 2014/35/EU (ref. NAC assessment of IEC 61010-1/A1).

2. In 15.1 as an alternative method, for interlock systems containing electric/electronic or programmable components (E/E/P components) the reliability and design requirements can be determined by applying, for example IEC 62061 (SIL) or ISO 13849 (PL).

Further technical development is reserved for a new amendment or edition to be initiated separately as necessary.

This alignment is realised as a new 3rd edition of IEC 61010-2-040 simply because of document control; the previous edition 2.0 is based on the third edition of IEC 61010-1:2010 (without the Amendment 1:2016) and amending it to incorporate the contents of IEC 61010-1 Amendment 1 would need an unnecessary repeating of the requirements in that amendment 1 that are not particular for the equipment in the scope of IEC 61010-2-040 . Furthermore, technically, one would need to follow 4 documents in parallel to get the full text of this part 2 (61010-1:2010, 61010-1 A1:2016, 61010-2-040:2015, and 61010-2-040 A1).With this approach, and when the consolidated version of IEC 61010-1:2010/A1:2016 conveniently is published, only two documents are needed.

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR  
MEASUREMENT, CONTROL, AND LABORATORY USE –**

120

121

122

**Part 2-040: Particular requirements for sterilizers and  
washer-disinfectors used to treat medical materials**

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## FOREWORD

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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61010-2-040 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

This third edition cancels and replaces the second edition published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) It is established on the basis of the third edition (2010) of IEC 61010-1 and its amendment 1 (2016)

b) Adaptation of text changes introduced by Amendment 1 of IEC 61010-1:2010;

c) Added tolerance for stability of a.c. voltage test equipment to Clause 6.8.3.1;



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

FDIS	Report on voting
66/xxx/FDIS	66/xxx/RVD

171  
172 Full information on the voting for the approval of this International Standard can be found in  
173 the report on voting indicated in the above table.

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

175 A list of all parts in the IEC 61010 series, published under the general title *Safety*  
176 *requirements for electrical equipment for measurement, control, and laboratory use*, can be  
177 found on the IEC website.

178 This Part 2-040 is intended to be used in conjunction with the latest edition of IEC 61010-1. It  
179 was established on the basis of the third edition (2010) of IEC 61010-1 and its amendment 1  
180 (2016), hereinafter referred to as Part 1.

181 This Part 2-040 supplements or modifies the corresponding clauses in Part 1 so as to convert  
182 that publication into the IEC standard: *Particular requirements for sterilizers and washer-*  
183 *disinfectors used to treat medical materials*.

184 Where a particular subclause of Part 1 is not mentioned in this Part 2-040, that subclause  
185 applies as far as is applicable. Where this Part 2-040 states "addition", "modification",  
186 "replacement", or "deletion", the relevant requirement, test specification or note in Part 1 shall  
187 be adapted accordingly.

188 In this standard: [oSIST prEN IEC 61010-2-040:2020](https://standards.iteh.ai/catalog/standards/sist/35b4e019-19f4-4cc8-814b-87976826c/osist-pren-iec-61010-2-040-2020)  
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189 1) the following print types are used: [87976826c/osist-pren-iec-61010-2-040-2020](https://standards.iteh.ai/catalog/standards/sist/35b4e019-19f4-4cc8-814b-87976826c/osist-pren-iec-61010-2-040-2020)

- 190 – requirements: in roman type;  
191 – NOTES: in small roman type;  
192 – conformity and tests: *in italic type*;  
193 – terms used throughout this standard which have been defined in Clause 3: SMALL  
194 ROMAN CAPITALS.  
195 2) subclauses, figures, and tables which are additional to those in Part 1 are numbered  
196 starting from 101; additional annexes are lettered starting from AA and additional list  
197 items are lettered from aa).

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

- 201 • reconfirmed,
- 202 • withdrawn,
- 203 • replaced by a revised edition, or
- 204 • amended.

205

206 **SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR**  
 207 **MEASUREMENT, CONTROL, AND LABORATORY USE –**

208  
 209 **Part 2-040: Particular requirements for sterilizers and**  
 210 **washer-disinfectors used to treat medical materials**  
 211  
 212  
 213

214 **1 Scope and object**

215 This clause of Part 1 is applicable except as follows:

216 **1.1.1 Equipment included in scope**

217 *Replacement:*

218 *Replace the existing text with the following:*

219 This part of IEC 61010 specifies safety requirements for electrical equipment intended for  
 220 sterilization, washing, and disinfection of medical materials in the medical, veterinary,  
 221 pharmaceutical and laboratory fields, when used under the environmental conditions of 1.4.

222 Examples of such equipment include the following:

- 223 a) sterilizers and disinfectors using steam, and/or hot water as the sterilant;  
 224 b) sterilizers and disinfectors using toxic gas, toxic aerosol or toxic vapour as the sterilant;  
 225 c) sterilizers and disinfectors using hot air or hot inert gas as the sterilant; and  
 226 d) washer disinfectors.

227 **1.1.2 Equipment excluded from scope**

228 *Addition:*

229 *Add the following note to item f):*

230 NOTE IEC 60601-1 defines medical electrical equipment as follows:

231 Electrical equipment, provided with not more than one connection to a particular supply MAINS and intended by its  
 232 manufacturer to be used in the diagnosis, treatment, or monitoring of a patient; and that makes physical or  
 233 electrical contact with the patient or transfers energy to or from the patient or detects such energy transfer to or  
 234 from the patient.

235 *Addition:*

236 *Add the following new second paragraph:*

237 This part of IEC 61010 does not apply to the following types of equipment:

- 238 aa) equipment for use in hazardous atmospheres (see IEC 60079) but does apply to an  
 239 atmosphere created inside equipment by a flammable sterilizing agent (see 13.0);  
 240 bb) laboratory equipment for the heating of materials for other purposes than sterilization or  
 241 disinfection (see IEC 61010-2-010);  
 242 cc) laundry equipment (see IEC 60335-2-4, IEC 60335-2-7, IEC 60335-2-11, and  
 243 ISO 10472), unless designed for disinfecting medical materials;  
 244 dd) dishwashers (see IEC 60335-2-5 and IEC 60335-2-58).

245 **1.2.1 Aspects included in scope**246 *Replacement:*247 *Replace item g) with the following new text:*248 g) liberated gases (including the non-intentional escape of toxic gas), pathogenic  
249 substances, explosion and implosion (see Clause 13).250 **1.2.2 Aspects excluded from scope**251 *Addition:*252 *Add the following two new items:*253 aa) special requirements for protection against chemical and high-risk micro-biological  
254 HAZARDS associated with the LOAD;

255 bb) general requirements for the design of calorifiers, shell boilers and PRESSURE VESSELS.

256 NOTE National and other regulations or codes apply for the safety of calorifiers, shell boilers and  
257 PRESSURE VESSELS (see 14.101).258 **2 Normative references**

259 This clause of Part 1 is applicable except as follows:

260 *Addition:*261 *Add the following new references:*262 IEC 61770, *Electric appliances connected to the water mains — Avoidance of back-siphonage*  
263 *and failure of hose-sets*264 ISO 3585, *Borosilicate glass 3.3 — Properties*265 ISO 4126-1, *Safety devices for protection against excessive pressure — Part 1: Safety valves*266 ISO 4126-2, *Safety devices for protection against excessive pressure – Part 2: Bursting disc*  
267 *safety devices*268 **3 Terms and definitions**

269 This clause of Part 1 is applicable except as follows:

270 **3.5.2**271 **HAZARD**272 *Addition:*273 *Add the following new note:*274 Note 1 to entry: In the context of this standard, the term HAZARD relates only to potential sources of  
275 harm to the OPERATOR and surroundings (see 1.2.1), and does not include potential sources of harm  
276 related to the efficacy of the process.

277 **3.5.11**278 **OPERATOR**279 *Addition:*280 *Add the following note:*281 Note 1 to entry: An OPERATOR includes persons installing, operating, adjusting, maintaining, cleaning, repairing or  
282 moving equipment.283 *Addition:*284 *Add the following new terms and definitions:*285 **3.2.101**286 **CHAMBER**

287 part of the equipment which receives the LOAD

288 **3.2.102**289 **LOAD**

290 equipment or materials put into a CHAMBER to be processed through an OPERATING CYCLE

291 **3.2.103**292 **STERILIZER**293 equipment designed to achieve sterilization which comprises a series of actions or operations  
294 needed to achieve the specified requirements for sterility295 **3.2.104**296 **PRESSURE VESSEL**297 assembly comprising the CHAMBER, the jacket (if fitted), doors, and all other components in  
298 permanent open connection with the CHAMBER299 Note 1 to entry: The PRESSURE VESSEL does not include parts from which it can be isolated, such as steam gene-  
300 rators, pipework, and fittings.301 **3.2.105**302 **OPERATING CYCLE**

303 complete set of stages of the process that is carried out, in a specified sequence

304 Note 1 to entry: Loading and unloading are not part of the OPERATING CYCLE.

305 **3.2.106**306 **WASHER-DISINFECTOR**307 equipment intended to clean and disinfect medical devices and other articles used in the  
308 context for example of medical, dental, pharmaceutical and veterinary practice309 **4 Tests**

310 This clause of Part 1 is applicable except as follows:

311 **4.3.2.4 Covers and removable parts**312 *Addition:*313 *Add the following new second paragraph:*314 Covers including panels and control box enclosures which do not require the use of a TOOL for  
315 removal need not be removed if they have interlocks which meet the requirements of

316 Clause 15, and which automatically de-activate all parts which would otherwise present a  
317 HAZARD when the cover is opened.

#### 318 **4.3.2.12 Duty cycle**

319 *Addition:*

320 *Add the following new second paragraph:*

321 Equipment which can be operated continuously shall also be tested without any interval  
322 between consecutive OPERATING CYCLES.

323 *Addition:*

324 *Add the following new subclause:*

#### 325 **4.3.2.101 Non-electrical supplies and services**

326 These shall be set to the least favourable RATED settings.

#### 327 **4.4.2.1 General**

328 *Replacement:*

329 *Replace the first sentence of the first paragraph by the following sentence:*

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330 Fault conditions shall include those specified in 4.4.2.2 to 4.4.2.14 and 4.4.2.101 to 4.4.2.103.

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331 **4.4.2.5 Motors** [https://standards.iteh.ai/catalog/standards/sist/35b4e019-19f4-4cc8-814b-  
86895098ee6c/osist-pren-iec-61010-2-040-2020](https://standards.iteh.ai/catalog/standards/sist/35b4e019-19f4-4cc8-814b-86895098ee6c/osist-pren-iec-61010-2-040-2020)

332 *Addition:*

333 *Add the following new second paragraph:*

334 If it is impracticable to test a motor in place, a separate identical motor can be tested but it  
335 shall be tested in conditions that meet or exceed the conditions within the equipment.

#### 336 **4.4.2.13 Interlocks**

337 *Addition:*

338 *Add the following new second paragraph:*

339 If an interlock provides protection against accidental contact with a hazardous substance, it is  
340 tested using a non-hazardous substance.

341 *Addition:*

342 *Add the following three new subclauses:*

#### 343 **4.4.2.101 Pressure controllers**

344 Pressure controllers, except for overpressure safety devices meeting the requirements of  
345 11.7.4, shall be overridden to supply the service continuously.