

**SLOVENSKI  
STANDARD**

**SIST EN 61010-2-041:1999**

prva izdaja  
julij 1999

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Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-041: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes (IEC 61010-2-041:1995)

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ICS 19.080; 71.040.10

3697b847adbd/sist-en-61010-2-041-1999

Referenčna številka  
SIST EN 61010-2-041:1999(en)

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ICS 19.080; 71.040.20

Descriptors: Safety, electrical equipment, autoclaves, medical material, laboratory processes

English version

**Safety requirements for electrical equipment for measurement,  
control, and laboratory use**  
**Part 2-041: Particular requirements for autoclaves using steam  
for the treatment of medical materials, and for laboratory processes**  
(IEC 1010-2-041:1996)

Règles de sécurité pour appareils  
électriques de mesure, de régulation  
et de laboratoire  
Partie 2-041: Prescriptions particulières  
pour autoclaves utilisant de la vapeur  
pour le traitement des matériels à usage  
médical et durant les procédés de  
traitement de laboratoire  
(CEI 1010-2-041:1996)

Sicherheitsbestimmungen für elektrische  
Meß-, Steuer-, Regel- und Laborgeräte  
Teil 2-041: Besondere Anforderungen  
an Dampf-Autoklaven für die  
Behandlung medizinischen Materials  
und für Laboranwendungen  
(IEC 1010-2-041:1996)

This European Standard was approved by CENELEC on 1996-03-05. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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**CENELEC**

European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

### Foreword

The text of document 66/120/FDIS, future edition 1 of IEC 1010-2-041, prepared by IEC TC 66, Safety of measuring, control, and laboratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61010-2-041 on 1996-03-05.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1996-12-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-12-01

For products which have complied with the relevant national standard before 1996-12-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2001-12-01.

This part 2 is to be used in conjunction with EN 61010-1:1993. Consideration may be given to future editions of, or amendments to, EN 61010-1.

This part 2 supplements or modifies the corresponding clauses of EN 61010-1. Where a particular clause or subclause of part 1 is not mentioned in this part 2, that clause or subclause applies as far as is reasonable. Where this part 2 states "addition", "modification" or "replacement", the relevant text of part 1 is to be adapted accordingly.

Annexes designated "normative" are part of the body of the standard. In this standard, annex ZA is normative. Annex ZA has been added by CENELEC.

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### Endorsement notice

The text of the International Standard IEC 1010-2-041:1996 was approved by CENELEC as a European Standard without any modification.

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**Annex ZA (normative)**

**Normative references to international publications  
with their corresponding European publications**

Addition to annex ZA of EN 61010-1:1993:

Add under "Other publications":

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 3585	1991	Borosilicate glass 3.3 - Properties	-	-
ISO 6718	1991	Bursting discs and bursting disc devices	-	-

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Corrigendum to 61010-2-041

English version

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Title page and page 2, Endorsement notice

Wherever document IEC 1010-2-041:1996 is mentioned (three times on the title page, once in the endorsement notice), replace "1996" by "1995".

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September 1996

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NORME  
INTERNATIONALE  
INTERNATIONAL  
STANDARD

CEI  
IEC  
1010-2-041

Première édition  
First edition  
1995-12

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PUBLICATION GROUPEE DE SÉCURITÉ  
GROUP SAFETY PUBLICATION

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**Règles de sécurité pour appareils électriques  
de mesure, de régulation et de laboratoire**

**Partie 2-041:**

Prescriptions particulières pour autoclaves  
utilisant de la vapeur pour le traitement  
des matériels à usage médical et durant  
les procédés de traitement de laboratoire

**Safety requirements for electrical equipment  
for measurement, control, and laboratory use**

**Part 2-041:**

Particular requirements for autoclaves using  
steam for the treatment of medical materials,  
and for laboratory processes

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Commission Electrotechnique Internationale  
International Electrotechnical Commission  
Международная Электротехническая Комиссия

CODE PRIX  
PRICE CODE

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● Pour prix, voir catalogue en vigueur  
For price, see current catalogue

## CONTENTS

	Page
FOREWORD .....	5
INTRODUCTION .....	9
Clause	
1 Scope and object .....	11
2 Normative references .....	13
3 Definitions .....	13
4 Tests .....	15
5 Marking and documentation .....	17
6 Protection against electric shock .....	23
7 Protection against mechanical hazards .....	25
8 Mechanical resistance to shock and impact .....	33
9 Equipment temperature limits and protection against the spread of fire .....	35
10 Resistance to heat .....	35
11 Protection against hazards from fluids .....	35
12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure .....	39
13 Protection against liberated gases, explosion and implosion .....	41
14 Components .....	41
15 Protection by interlocks .....	45
16 Measuring circuits .....	45
Annexes .....	47



## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE

### Part 2-041: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes

## FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.
- 3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
- 4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
- 5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

International Standard IEC 1010-2-041 has been prepared by IEC technical committee 66: Safety of measuring, control, and laboratory equipment.

It has the status of a group safety publication in accordance with IEC Guide 104.

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

SIST EN 61010-2-041:1999	
FDIS	Report on voting
<a href="https://standards.iteh.ai/catalog/standards/sist/c7891d96-4dac-4910-ad16-3697b847adhd/sist-en-61010-2-041-1999">https://standards.iteh.ai/catalog/standards/sist/c7891d96-4dac-4910-ad16-3697b847adhd/sist-en-61010-2-041-1999</a>	
66/120/FDIS	66/138/RVD

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 part 2 is intended to be used in conjunction with IEC 1010-1. It was established on the basis of the first edition (1990) and its amendment 1 (1991). Consideration may be given to future editions of, or amendments to, IEC 1010-1.

This part 2 supplements or modifies the corresponding clauses in IEC 1010-1 so as to convert that publication into the IEC standard: *Safety requirements for AUTOCLAVES using steam for the treatment of medical materials, and for laboratory processes.*

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.

In this standard, the following print types are used:

- requirements: in roman type;
- NOTES: in small roman type;
- *conformity*: in italic type;
- terms used throughout this standard which have been defined in clause 3: SMALL ROMAN CAPITALS.

The word "*Conformity*" is used throughout this standard instead of "*Compliance*" in accordance with the requirements of ISO/IEC Guide 2: 1991, and all references in part 1 to "*Compliance*" should therefore be read as "*Conformity*". Part 1 will be changed to reflect "*Conformity*" when its next edition is published.

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## INTRODUCTION

This part 2 of IEC 1010 is required because of the special attention which has to be given to features of equipment which makes use of steam above or below atmospheric pressure for its function. This equipment as a result has many potentially hazardous parts in its construction which demand different requirements for safety, which supplement or modify those which are stated in part 1.

It has to be recognized that other national and international standards and regulations exist, which need to be considered since they may supplement this standard.

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## SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE

### Part 2-041: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes

#### 1 Scope and object

This clause of part 1 is applicable except as follows:

##### 1.1 Scope

###### *Replacement:*

This standard applies to AUTOCLAVES, including those with an automatic loading and unloading system, which incorporate a PRESSURE VESSEL using steam within the absolute pressure range from 0 to 500 kPa, and intended for the treatment of medical materials and for laboratory processes, for example for sterilization.

###### NOTES

- 1 National and other regulations or codes apply for the safety of automatic loading and unloading systems.
- 2 All pressures are specified in absolute terms. Atmospheric pressure (1 bar) = 100 kPa.

Where an AUTOCLAVE incorporates a steam generator having its own PRESSURE VESSEL within the same enclosure, the applicable safety requirements for the AUTOCLAVE PRESSURE VESSEL apply also to the steam generator (see 14.105).

##### 1.1.2 Equipment excluded from the scope

###### *Addition:*

*Add the following new dash:*

- pressurized environmental cabinets.

###### NOTES

- 1 Since all AUTOCLAVES covered by this part 2 use steam, other types using dry heat, toxic gas or radiation are not included.
- 2 This standard does not deal with special requirements for protection against chemical and high-risk micro-biological hazards associated with the AUTOCLAVE LOAD, nor with requirements for the design of the PRESSURE VESSEL itself.

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##### 1.4 Environmental conditions

###### *Replacements:*

*Replace the first dash by the following new dash:*

- indoor use, and outdoor use for AUTOCLAVES if specified by the manufacturer (see 11.6 of part 1).

*Replace the fourth dash by the following new dash:*

- maximum relative humidity 85 % at any temperature between 5 °C and 40 °C.