

ELEKTRILISED MEDITSIINISEADMED. OSA 2-18:  
ERINÕUDED ENDOSKOOPIASEADME ESMASELE  
OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-18: Particular  
requirements for the basic safety and essential  
performance of endoscopic equipment

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-18:2015 sisaldab Euroopa standardi EN 60601-2-18:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-18:2015 consists of the English text of the European standard EN 60601-2-18:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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English Version

**Medical electrical equipment - Part 2-18: Particular requirements  
for the basic safety and essential performance of endoscopic  
equipment  
(IEC 60601-2-18:2009)**

Appareils électromédicaux - Partie 2-18: Exigences  
particulières pour la sécurité de base et les performances  
essentielles des appareils d'endoscopie  
(IEC 60601-2-18:2009)

Medizinische elektrische Geräte - Teil 2-18: Besondere  
Festlegungen für die Sicherheit einschließlich der  
wesentlichen Leistungsmerkmale von endoskopischen  
Geräten  
(IEC 60601-2-18:2009)

This European Standard was approved by CENELEC on 2015-09-15. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

## European foreword

The text of document 62D/682/CDV, future edition 3 of IEC 60601-2-18, prepared by SC 62D "Electromedical equipment", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-18:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-06-15
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-09-15

This document supersedes EN 60601-2-18:1996.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

## Endorsement notice

The text of the International Standard IEC 60601-2-18:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated :

IEC 60601-2-57	NOTE	Harmonized as EN 60601-2-57.
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## Annex ZA

(normative)

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

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: [www.cenelec.eu](http://www.cenelec.eu).

#### ***Annex ZA of EN 60601-1:2006 applies, except as follows:***

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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#### ***Replacement in Annex ZA of EN 60601-1:2006:***

IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corrigendum Mar.	2007 2010
-	-			

#### ***Addition to Annex ZA of EN 60601-1:2006:***

IEC 60601-2-2	2009	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2 + A11	2009 2011
-	-			
IEC 60601-2-37	-	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	EN 60601-2-37	-
ISO 8600-1	-	Optics and photonics - Medical endoscopes and endotherapy devices - Part 1: General requirements	-	-

**Annex ZZ**  
(informative)

**Coverage of Essential Requirements of EU Directives**

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

**WARNING:** Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

## CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
201.1 Scope, object and related standards .....	8
201.2 Normative references .....	9
201.3 Terms and definitions.....	10
201.4 General requirements.....	12
201.5 General requirements for testing of ME EQUIPMENT.....	14
201.6 Classification of ME EQUIPMENT and ME SYSTEMS .....	14
201.7 ME EQUIPMENT identification, marking and documents.....	14
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	18
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	19
201.10 Protection against unwanted and excessive radiation HAZARDS.....	20
201.11 Protection against excessive temperatures and other HAZARDS.....	21
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	24
201.13 HAZARDOUS SITUATIONS and fault conditions.....	25
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) .....	25
201.15 Construction of ME EQUIPMENT .....	25
201.16 ME SYSTEMS .....	26
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS .....	26
202 Electromagnetic compatibility – Requirements and tests .....	26
Annexes .....	27
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	27
Annex D (informative) Symbols on marking.....	29
Annex J (informative) Survey of insulation paths.....	31
Annex AA (informative) Particular guidance and rationale.....	33
Annex BB (informative) Clauses of this standard addressing essential principles of safety and performance of medical devices (GHTF/SG1/N41R9:2005).....	43
Index of defined terms used in this particular standard.....	45
Figure 201.101 – Identification of LIGHT EMISSION PART .....	12
Figure 201.102 – Measurement of CAPACITIVELY-COUPLED HF CURRENT from conductive parts of an ENDOSCOPE.....	24
Figure 201.J.101 – Insulation example 101 .....	31
Figure 201.J.102 – Insulation example 102 .....	32
Figure 201.J.103 – Insulation example 103 .....	32
Figure AA.101 – Illustration of typical CONFIGURATION FOR ENDOSCOPIC APPLICATION .....	34
Table 201.101 – List of ESSENTIAL PERFORMANCE requirements .....	13

Table 201.C.101 – Marking on the outside of ENDOSCOPIC EQUIPMENT or its parts .....	27
Table 201.C.102 – Marking on the inside of ENDOSCOPIC EQUIPMENT or its parts .....	27
Table 201.C.104 – ACCOMPANYING DOCUMENTS, general .....	28
Table 201.C.105 – ACCOMPANYING DOCUMENTS, instructions for use .....	28
Table 201.D.101 – Symbols for marking ENDOSCOPIC EQUIPMENT or its parts.....	29
Table BB.1 – Correspondence between this standard and GHTF/SG1/N41R9:2005 .....	43



## INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of endoscopic equipment.

This particular standard amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as 'the general standard'.

The requirements are followed by specifications for the relevant tests.

## MEDICAL ELECTRICAL EQUIPMENT –

### Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1)</sup> applies, except as follows:

##### 201.1.1 \* Scope

*Replacement:*

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ENDOSCOPIC EQUIPMENT together with its INTERCONNECTION CONDITIONS and INTERFACE CONDITIONS.

##### 201.1.2 Object

*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ENDOSCOPIC EQUIPMENT [as defined in 201.3.204].

NOTE This object includes endoscopic intense light source equipment which is part of the ENDOSCOPIC EQUIPMENT including its supply unit, therefore IEC 60601-2-57 does not apply.

##### 201.1.3 Collateral standards

*Addition:*

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

##### 201.1.4 Particular standards

*Replacement:*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

<sup>1)</sup> The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.