BSI Standards Publication

Medical electrical equipment

Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

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National foreword

This British Standard is the UK implementation of EN IEC 60601-2-22:2020+A11:2026. It is identical to IEC 60601-2-22:2019. It supersedes BS EN 60601-2-22:2020, which will be withdrawn on 31 January 2029.

The start and finish of text introduced or altered by amendment A11 is indicated in the text by tags. Tags indicating changes to CENELEC text carry the number of the CENELEC amendment. For example, text altered by CENELEC amendment A11 is indicated by ⟨A11⟩ ⟨A11⟩.

The UK participation in its preparation was entrusted to Technical Committee EPL/76, Optical radiation safety and laser equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

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UK Government is responsible for legislation. For information on legislation and policies relating to that legislation, consult the relevant pages of www.gov.uk.

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Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2020.

Amendments/corrigenda issued since publication

Date	Text affected
31 January 2026	Implementation of CENELEC amendment A11:2026

EUROPEAN STANDARD **EN IEC 60601-2-22:2020+A11**

EUROPÄISCHE NORM

January 2026

ICS 11.040.01; 31.260

Supersedes EN 60601-2-22:2013 and all of its amendments and corrigenda (if any)

English Version

Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment (IEC 60601-2-22:2019)

Appareils electromedicaux - Partie 2-22: Exigences particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux, esthétiques, thérapeutiques et de diagnostic à laser (IEC 60601-2-22:2019)

Medizinische elektrische Geräte - Teil 2-22: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für chirurgische, therapeutische und diagnostische Lasergeräte (IEC 60601-2-22:2019)

This European Standard was approved by CENELEC on 2019-12-25. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

The text of document 76/580/CDV, future edition 4 of IEC 60601-2-22, prepared by IEC/TC 76 "Optical radiation safety and laser equipment" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-22:2020.

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) 2021-04-30
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-10-30

This document supersedes EN 60601-2-22:2013 and all of its amendments and corrigenda (if any).

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

Endorsement notice

The text of the International Standard IEC 60601-2-22:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60335-2-113:2016	NOTE	Harmonized as EN 60335-2-113:—[1]
IEC 61010-1	NOTE	Harmonized as EN 61010-1
IEC 60947-3	NOTE	Harmonized as EN 60947-3

[1] Under preparation. Stage at time of publication: FprEN 60335-2-113:2019.

European foreword to Amendment A11

This document (EN IEC 60601-2-22:2020/A11:2026) has been prepared by CLC/TC 76 "Optical radiation safety and laser equipment".

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2027-01-31
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2029-01-31

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

This document has been prepared under a standardization request addressed to CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZZ, which is an integral part of this document.

Collateral standards in the IEC 60601 series are numbered IEC 60601-1-xx. The IEC maintains a catalogue of valid International Standards. Users of this document can consult this catalogue at "http://webstore.iec.ch" to determine which collateral standards have been published.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

⟨A11⟩ Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where 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.cencenelec.eu.

The Annex ZA of EN 60601-1:2006/A13:2024 applies with the following additions:

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
			+ A1:2013/AC	2014
-	-		+ A12	2014
			+ A2	2021
			+ AC	2022-12
			+ A13	2024
IEC 60825-1	2014	Safety of laser products - Part 1: Equipment classification and requirements	EN 60825-1	2014
-	-		+ AC	2017-06
			+ A11	2021
			+ A11:2021/AC	2022-03

⟨A11⟩

⟨A11⟩ Annex ZZ
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex ZZ. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZZ.1, it means that it is not addressed by this European Standard.