

Official Journal of the European Union

L 1



English edition

Legislation

Volume 65

5 January 2022

Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2022/2 of 4 January 2022 correcting the French language version of Implementing Regulation (EU) No 1207/2011 laying down requirements for the performance and the interoperability of surveillance for the single European sky ⁽¹⁾ 1**
- ★ **Commission Implementing Regulation (EU) 2022/3 of 4 January 2022 correcting certain language versions of Annex II to Implementing Regulation (EU) 2015/1018 laying down a list classifying occurrences in civil aviation to be mandatorily reported according to Regulation (EU) No 376/2014 of the European Parliament and of the Council ⁽¹⁾ 3**
- ★ **Commission Implementing Regulation (EU) 2022/4 of 4 January 2022 approving the active substance *Purpureocillium lilacinum* strain PL11 as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 ⁽¹⁾ 5**
- ★ **Commission Implementing Regulation (EU) 2022/5 of 4 January 2022 amending for the 325th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations 9**

DECISIONS

- ★ **Commission Implementing Decision (EU) 2022/6 of 4 January 2022 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment 11**

⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2

of 4 January 2022

correcting the French language version of Implementing Regulation (EU) No 1207/2011 laying down requirements for the performance and the interoperability of surveillance for the single European sky**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ⁽¹⁾ and in particular Article 44(1)(a) thereof,

Whereas:

- (1) The French language version of Commission Implementing Regulation (EU) No 1207/2011 ⁽²⁾ contains errors in Article 5(5), second subparagraph, point (iii) and in Article 8(8) that alter the meaning of the text.
- (2) The French language version of Implementing Regulation (EU) No 1207/2011 should therefore be corrected accordingly. The other language versions are not affected.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 127(1) of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

*Article 1**(does not concern the English language)**Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 1207/2011 of 22 November 2011 laying down requirements for the performance and the interoperability of surveillance for the single European sky (OJ L 305, 23.11.2011, p. 35).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 January 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/3**of 4 January 2022****correcting certain language versions of Annex II to Implementing Regulation (EU) 2015/1018 laying down a list classifying occurrences in civil aviation to be mandatorily reported according to Regulation (EU) No 376/2014 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 ⁽¹⁾, and in particular Article 4(5) thereof,

Whereas:

- (1) The Bulgarian, Estonian and Slovenian language versions of Annex II to Commission Implementing Regulation (EU) 2015/1018 ⁽²⁾ contain an error in section 3, point 17 as regards the scope of the provision.
- (2) The Bulgarian, Estonian and Slovenian language versions of Annex II to Implementing Regulation (EU) 2015/1018 should therefore be corrected accordingly. The other language versions are not affected.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 127 of Regulation (EU) 2018/1139 of the European Parliament and of the Council ⁽³⁾,

HAS ADOPTED THIS REGULATION:

Article 1

(does not concern the English language)

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 122, 24.4.2014, p. 18.

⁽²⁾ Commission Implementing Regulation (EU) 2015/1018 of 29 June 2015 laying down a list classifying occurrences in civil aviation to be mandatorily reported according to Regulation (EU) No 376/2014 of the European Parliament and of the Council (OJ L 163, 30.6.2015, p. 1).

⁽³⁾ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 January 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/4**of 4 January 2022**

approving the active substance *Purpureocillium lilacinum* strain PL11 as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009, of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾ and in particular Article 13(2) in conjunction with Article 22(1) thereof,

Whereas:

- (1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 LAM International Corp submitted to the United Kingdom on 16 December 2014 an application for the approval of the active substance *Purpureocillium lilacinum* strain PL11.
- (2) In accordance with Article 9(3) of that Regulation, the United Kingdom as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 17 March 2015 of the admissibility of the application.
- (3) On 27 March 2019, UK as the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. Denmark replaced the United Kingdom as rapporteur Member State on the 1 January 2020 due to the withdrawal of the United Kingdom from the Union.
- (4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 27 November 2020.
- (5) On 20 December 2020 the Authority communicated to the applicant, the Member States and the Commission its conclusion ⁽²⁾ on whether the active substance *Purpureocillium lilacinum* strain PL11 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.
- (6) The Commission presented a review report and a draft Regulation regarding *Purpureocillium lilacinum* strain PL11 to the Standing Committee on Plants, Animals, Food and Feed on 23 March 2021 and on 5 July 2021, respectively.
- (7) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 13(1) of Regulation (EC) No 1107/2009, on the review report. The applicant submitted its comments, which have been carefully examined.
- (8) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA Journal 2021;19(1):6393, 17 pp. doi:10.2903/j.efsa.2021.6393.

- (9) The Commission further considers that *Purpureocillium lilacinum* strain PL11 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009 as it fulfils the conditions set in Annex II point 5.2 to Regulation (EC) No 1107/2009.
- (10) It is therefore appropriate to approve *Purpureocillium lilacinum* strain PL11 as a low-risk substance.
- (11) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions.
- (12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾ should be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of the active substance

The active substance *Purpureocillium lilacinum* strain PL11 is approved as set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 January 2022.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
<i>Purpureocillium lilacinum</i> strain PL11	Not applicable	No relevant impurities	25 January 2022	24 January 2037	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Purpureocillium lilacinum</i> strain PL11 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾; b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

⁽²⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.

ANNEX II

In Part D of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

'34	<i>Purpureocillium lilacinum</i> strain PL11	Not applicable	No relevant impurities	25 January 2022	24 January 2037	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Purpureocillium lilacinum</i> strain PL11 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (*); b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.
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(*) https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.

COMMISSION IMPLEMENTING REGULATION (EU) 2022/5**of 4 January 2022****amending for the 325th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations ⁽¹⁾, and in particular Article 7(1)(a) and Article 7a(1) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.
- (2) On 29 December 2021, the Sanctions Committee of the United Nations Security Council decided to add two entries to the list of persons, groups and entities to whom the freezing of funds and economic resources should apply.
- (3) Annex I to Regulation (EC) No 881/2002 should therefore be amended accordingly.
- (4) In order to ensure that the measures provided for in this Regulation are effective it should enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 January 2022.

*For the Commission,
On behalf of the President,
Director-General
Directorate-General for Financial Stability, Financial
Services and Capital Markets Union*

⁽¹⁾ OJ L 139, 29.5.2002, p. 9.

ANNEX

- (1) In Annex I to Regulation (EC) No 881/2002 the following entry is added under the heading 'Natural persons':

'Ashraf Al-Qizani (original script: أشرف القيزاني) (good quality alias: (a) Ashraf al-Gizani; (b) Abu 'Ubaydah al-Kafi; (c) Achref Ben Fethi Ben Mabrouk Guizani; (d) Achraf Ben Fathi Ben Mabrouk Guizani). Date of birth: 5.10.1991. Place of birth: El Gouazine, Dahmani, Governorate of Le Kef, Tunisia. Nationality: Tunisia. National identification no: 13601334, Tunisia. Other information: Senior member of Islamic State in Iraq and the Levant (ISIL), listed as Al-Qaida in Iraq. Recruited for ISIL and instructed individuals to perpetrate terrorist acts via online video. Date of designation referred to in Article 7d(2)(i): 29.12.2021.'

- (2) In Annex I to Regulation (EC) No 881/2002 the following entry is added under the heading 'Legal persons, groups and entities':

'Jund Al-Khilafah in Tunisia (JAK-T) (original script: جند الخلافة في تونس) (alias: (a) ISIL-Tunisia; (b) ISIL-Tunisia Province; (c) Soldiers of the Caliphate; (d) Jund al-Khilafa; (e) Jund al Khilafah; (f) Jund al-Khilafah fi Tunis; (g) Soldiers of the Caliphate in Tunisia; (h) Tala I Jund al-Khilafah; (i) Vanguard of the Soldiers of the Caliphate; (j) Daesh Tunisia; (k) Ajnad). Other information: Formed in November 2014. Associated with Islamic State in Iraq and the Levant, listed as Al-Qaida in Iraq. Date of designation referred to in Article 7d(2)(i): 29.12.2021.'

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2022/6

of 4 January 2022

amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ⁽¹⁾, and in particular Article 10(6) thereof,

Whereas:

- (1) In accordance with Article 8(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council ⁽²⁾, devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, are to be presumed to be in conformity with the requirements of that Regulation covered by those standards or parts thereof.
- (2) Regulation (EU) 2017/745 replaced Council Directives 90/385/EEC ⁽³⁾ and 93/42/EEC ⁽⁴⁾ from 26 May 2021.
- (3) By Implementing Decision C(2021) 2406 ⁽⁵⁾, the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) for the revision of existing harmonised standards on medical devices developed in support of Directives 90/385/EEC and 93/42/EEC and the drafting of new harmonised standards in support of Regulation (EU) 2017/745.
- (4) On the basis of the request set out in Implementing Decision C(2021) 2406, CEN and Cenelec revised the harmonised standards EN ISO 10993-9:2009, EN ISO 10993-12:2012, EN ISO 11737-1:2018, EN ISO 13408-6:2011, EN ISO 13485:2016, EN ISO 14160:2011, EN ISO 15223-1:2016, EN ISO 17664:2017 and EN IEC 60601-2-83:2020, in order to take into account the latest technical and scientific progress and to adapt them to the requirements of Regulation (EU) 2017/745. This resulted in the adoption of the revised harmonised standards EN ISO 10993-9:2021 and EN ISO 10993-12:2021 on biological evaluation of medical devices, EN ISO 13408-6:2021 on aseptic processing of health care products, EN ISO 14160:2021 on sterilization of health care products, EN ISO 15223-1:2021 on symbols to be used with information to be supplied by the manufacturer and

⁽¹⁾ OJ L 316, 14.11.2012, p. 12.

⁽²⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁽³⁾ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

⁽⁴⁾ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

⁽⁵⁾ Commission Implementing Decision C(2021) 2406 of 14 April 2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council.

EN ISO 17664-1:2021 on processing of health care products and of amendment EN ISO 11737-1:2018/A1:2021 to harmonised standard EN ISO 11737-1:2018 on sterilization of health care products, amendment EN ISO 13485:2016/A11:2021 to harmonised standard EN ISO 13485:2016 on quality management systems and amendment EN IEC 60601-2-83:2020/A11:2021 to harmonised standard EN IEC 60601-2-83:2020 on particular requirements for the basic safety and essential performance of home light therapy equipment.

- (5) The Commission together with CEN and Cenelec has assessed whether the harmonised standards revised by CEN and Cenelec comply with the request set out in Implementing Decision C(2021) 2406.
- (6) The harmonised standards EN ISO 10993-9:2021, EN ISO 10993-12:2021, EN ISO 13408-6:2021, EN ISO 14160:2021, EN ISO 15223-1:2021 and EN ISO 17664-1:2021 and the amendments EN ISO 11737-1:2018/A1:2021, EN ISO 13485:2016/A11:2021 and EN IEC 60601-2-83:2020/A11:2021 satisfy the requirements which they aim to cover and which are set out in Regulation (EU) 2017/745. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.
- (7) The Annex to Commission Implementing Decision (EU) 2021/1182 ⁽⁶⁾ lists the references of harmonised standards drafted in support of Regulation (EU) 2017/745. In order to ensure that the references of harmonised standards drafted in support of Regulation (EU) 2017/745 are listed in one act, the references of standards EN ISO 10993-9:2021, EN ISO 10993-12:2021, EN ISO 13408-6:2021, EN ISO 14160:2021, EN ISO 15223-1:2021 and EN ISO 17664-1:2021 and the amendments EN ISO 11737-1:2018/A1:2021, EN ISO 13485:2016/A11:2021 and EN IEC 60601-2-83:2020/A11:2021 should be included in that Implementing Decision.
- (8) Implementing Decision (EU) 2021/1182 should therefore be amended accordingly.
- (9) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2021/1182 is amended in accordance with the Annex to this Decision.

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 4 January 2022.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁶⁾ Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council (OJ L 256, 19.7.2021, p. 100).

ANNEX

In the Annex to Implementing Decision (EU) 2021/1182, the following entries are added:

No	Reference of the standard
‘6.	EN ISO 10993-9:2021 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)
7.	EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
8.	EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018) EN ISO 11737-1:2018/A1:2021
9.	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)
10.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/A11:2021
11.	EN ISO 14160:2021 Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2020)
12.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
13.	EN ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)
14.	EN IEC 60601-2-83:2020 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment EN IEC 60601-2-83:2020/A11:2021’.

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN