Ministry of Health

ORDER no. 3362
of 29 September 2023

on approval of the list of Romanian standards adopting the harmonised European standards in the field of in vitro diagnostic medical devices falling under the scope of Regulation (EU) 2017/745, as well as the list of Romanian standards adopting the European harmonised standards in the field of in vitro diagnostic medical devices falling under the scope of Regulation (EU) 2017/746

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On seeing approval report no. AR/17.879/2023 of the Pharmaceutical and Medical Devices Directorate and the notification of the National Agency for Medicines and Medical Devices of Romania no. 105.489E of 10.03.2023, registered at the Ministry of Health with no. Reg2/5.850 din 14.03.2023,

taking into account the provisions of:

- Art. 7 paragraph (1) of Emergency Government Ordinance no. 46/2021 on establishment of an institutional framework and measures for enforcement of 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;
- Art. 5 of Emergency Government Ordinance no. 137/2022 on establishment of an institutional framework and measures for enforcement of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;
- Art. 932 paragraphs (1) and (2) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented;
- Art. 4 paragraph (4) points 1 and 28 of Law no. 134 of 12 July 2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented,

pursuant to Article 7 (4) of Government Decision No. 144/2010 on organisation and operation of the Ministry of Health, as further amended and supplemented,

the minister of health hereby issues the following Order:

Art. 1 – The List of Romanian standards adopting the harmonised European standards in the field of in vitro diagnostic medical devices falling under the scope of Regulation, whose references have been published in the Official Journal of the European Union, mentioned in Annex 1, for enforcement of the provisions of Art. 7 paragraph (1) of Emergency Government Ordinance no. 46/2021 on establishment of an institutional framework and measures for enforcement of 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, is approved.

Art. 2 - The list of Romanian standards adopting the European harmonised standards in the field of in vitro diagnostic medical devices falling under the scope of Regulation (EU) 2017/746, the references of which have been published in the Official Journal of the European Union, set out in Annex 2, for enforcement of the provisions of art. 5 of Emergency Government Ordinance no. 137/2022 on establishment of an institutional framework and measures for enforcement of provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, is approved.

Art. 3 – On entry into force of this Order, Order of the Minister of Health no. 355/2004 on approval of the list of Romanian standards adopting the harmonised European standards in the field of in vitro diagnostic medical devices, published in the Official Gazette of Romania, Part I, no. 343 of 20 April 2004, as further amended, as well as Order of the Minister of Health no. 1.163/2010 on approval of the list of Romanian standards adopting the harmonised European standards in the field of in vitro diagnostic medical devices, published in the Official Gazette of Romania, Part I, no. 631 of 8 September 2010, are repealed.

Art. 4 – Annexes 1 and 2 are integral part of this Order.

Art. 5 – This Order shall be published in the Official Gazette of Romania, Part I.

Minister of health,
Alexandru Rafila

ANNEX 1

LIST
of Romanian standards adopting the harmonised European standards in the field of in vitro diagnostic medical devices falling under the scope of Regulation (EU) 2017/745

No.	Standard indicator	Standard name	Date from which the presumption of compliance begins
1	SR EN 285+A1:2021	Sterilization. Steam sterilizers. Large sterilizers	17.05.2022
2	SR EN ISO 10993-9:2021	Biological evaluation of medical devices. Part 9: Framework for identification and quantification of potential degradation products	5.01.2022
3	SR EN ISO 10993-12:2021	Biological evaluation of medical devices. Part 12: Sample preparation and reference materials	5.01.2022
4	SR EN ISO 10993-23:2021	Biological evaluation of medical devices. Part 23: Tests for irritation	19.07.2021
5	SR EN ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	19.07.2021
	SR EN ISO 11135:2014/A1:2020	Sterilization of health-care products — Ethylene oxide Amendment 1: Revision of Annex E, Single batch release Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	

		Amendment 1: Revision of Annex E, Single batch release	
6	SR EN ISO 11137-1:2015	Sterilization of health care products — Radiation Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	19.07.2021
	SR EN ISO 11137-1:2015/A2:2020	Sterilization of health care products — Radiation Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices Amendment 2: Revision of 4.3.4 and 11.2	
7	SR EN ISO 11737-1:2018	Sterilization of health care products — Microbiological methods Part 1: Determination of a population of microorganisms on products	5.01.2022
	SR EN ISO 11737-1:2018/A1:2021	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products Amendment 1	
8	SR EN ISO 11737-2:2020	Sterilization of health care products. Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	19.07.2021
9	SR EN ISO 13408-6:2021	Aseptic processing of health care products Part 6: Isolator systems	5.01.2022

10	SR EN ISO 13485:2016 SR EN ISO 13485:2016/A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes Medical devices — Quality management systems — Requirements for regulatory purposes	5.01.2022
11	SR EN ISO 13485:2016 SR EN ISO 13485:2016/A11:2021 SR EN ISO 13485:2016/AC:2018	Medical devices — Quality management systems — Requirements for regulatory purposes Medical devices — Quality management systems — Requirements for regulatory purposes Medical devices — Quality management systems — Requirements for regulatory purposes	17.05.2022
12	SR 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	5.01.2022
13	SR EN ISO 14971:2020 SR EN ISO 14971:2020/A11:2022	Medical devices — Application of risk management to medical devices Medical devices — Application of risk management to medical devices	17.05.2022
14	SR EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	5.01.2022

15	SR 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	5.01.2022
16	SR EN ISO 25424:2020	Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices	19.07.2021
17	SR EN IEC 60601-2-83:2020 SR EN IEC 60601-2-83:2020/A11:2021	Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	5.01.2022

ANNEX 2

LIST
of Romanian standards adopting the European harmonised standards in the field of in vitro diagnostic medical devices falling under the scope of Regulation (EU) 2017/746

No.	Standard indicator	Standard name	Date from which the presumption of compliance begins
1	SR EN ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	20.07.2021
	SR EN ISO 11135:2014/A1:2020	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release	
2	SR EN ISO 11137-1:2015	Sterilization of health care products — Radiation Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	20.07.2021
	SR EN ISO 11137-1:2015/A2:2020	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 2: Revision	

		to 4.3.4 and 11.2	
3	SR EN ISO 11737-1:2018 SR EN ISO 11737-1:2018/A1:2021	Sterilization of health care products — Microbiological methods Part 1: Determination of a population of microorganisms on products Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products Amendment 1	7.01.2022
4	SR EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	20.07.2021
5	SR EN ISO 13408-6:2021	Aseptic processing of health care products Part 6: Isolator systems	7.01.2022
6	SR EN ISO 13485:2016 SR EN ISO 13485:2016/A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes Medical devices — Quality management systems — Requirements for regulatory purposes	7.01.2022
7	SR 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	7.01.2022

8	SR EN ISO 14971:2020 SR EN ISO 14971:2020/A11:2022	Medical devices — Application of risk management to medical devices Medical devices - Application of risk management to medical devices	12.05.2022
9	SR EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	7.01.2022
10	SR EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	7.01.2022
11	SR EN ISO 25424:2020	Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices	20.07.2021