THE DEPARTMENT OF HEALTH AND SOCIAL CARE
NOTICE OF PROPOSAL TO PUBLISH
0128/26
of 19 December 2025

references to standards for in vitro diagnostic medical devices in support of the Medical Devices Regulations 2002 (S.I. 2002/618)

1. This notice sets out proposals that:

(a) The references to standards listed in Annex I to this notice be published for the purposes of regulation 3A of S.I. 2002/618 in accordance with paragraph 2 below, and that the list of published standards set out in set out in Annex I to notice 0033/21 be amended in accordance with Annex I to this notice.

(b) The list of references to standards to be removed from publication, set out in Annex II to notice 0033/21, is amended in accordance with Annex II to this notice.

2. The references to standards are proposed to be published and accordingly designated under regulation 3A of S.I. 2002/618 at 00.01 on the 29th day beginning with the date of this notice, unless this notice is withdrawn or amended before that date. Any objection to the proposed publication for this purpose may be made to designatedstandards@businessandtrade.gov.uk

ANNEX I

The list of published standards as set out in Annex I to notice 0033/21 is proposed to be amended as follows:

(1) rows 1, 2, 5, 6, 8, 14, 17, 26, 30, 31, 40 and 44 are replaced by the following:

1.	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” - Part 1: Requirements for terminally sterilized medical devices
2.	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” - Part 2: Requirements for aseptically processed medical devices
5.	EN ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose EN ISO 11137-2:2015/A1:2023
6.	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
8.	EN ISO 13408-1:2024 Aseptic processing of health care products - Part 1: General requirements
14.	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems
17.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/A11:2021
26.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices EN ISO 14971:2019/A11:2021
30.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
31.	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

40.	EN ISO 25424:2019 Sterilisation of health care products – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilisation process for medical devices EN ISO 25424:2019/A1:2022
44.	EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices EN 62366-1:2015/A1:2020

(2) the following row is added:

45.	EN ISO 20916:2024 In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice

(3) rows 3, 9 and 16 are deleted.

ANNEX II

The list of standards for removal from publication, as set out in Annex II to notice 0033/21, is proposed to be amended as follows:

(1) rows 1 to 3 inclusive are removed.