

Standards for In-Vitro Diagnostic Medical Devices (98/79/EC)

European Standards (EN) as listed in the Official Journal of the European Union (the 'OJ') as forming the list drawn up by common agreement between the bodies notified by the Member States, under Article 5 of the Directive.

When the standards in the following table are adopted in the UK, they are prefixed with the letters BS EN.

Standard Number /issue date of Std	Official Journal Reference No.	Title	BS Adoptions
CEN EN 375:2001	OJ2002/C182/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use	BS EN 375:2001
CEN EN 376:2002	OJ2002/C182/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04	Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing	BS EN 376:2002
CEN EN 556-1:2001 /AC:2006	OJ2002/C182/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Sterilisation of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 1:Requirements for terminally sterilised medical devices	BS EN 556-1:2001 (corrigendum included)

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CEN EN 556-2:2003	OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	BS EN 556-2:2003
CEN EN 591:2001	OJ2002/C182/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04	Instructions for use for in vitro diagnostic instruments for professional use	BS EN 591:2001
CEN EN 592:2002	OJ2002/C182/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04	Instructions for use for in vitro diagnostic instruments for self-testing	BS EN 592:2002
CEN EN 980:2008	OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Symbols for use in the labelling of medical devices	BS EN 980:2008
CEN EN ISO 4135:2001	OJ2002/C182/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03	Anaesthetic and respiratory equipment — Vocabulary (ISO 4135:2001)	BS EN ISO 4135:2001
CEN EN ISO 10993-14:2009	OJ2009/C293/04	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)	BS EN ISO 10993-14:2009

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CEN EN ISO 10993-15:2009	OJ2009/C293/04	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)	BS EN ISO 10993-15:2009
CEN EN ISO 11737-2:2009	OJ2010/C183/04	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)	BS EN ISO 11737-2:2009
CEN EN 12286:1998 + Amendment A1:2000	OJ2001/C319/04 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Presentation of reference measurement procedures	BS EN 12286:1999 (Amendment incorporated)
CEN EN 12287:1999	OJ2000/C293/10 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Description of reference materials	BS EN 12287:1999
CEN EN 12322:1999 + Amendment A1:2001	OJ2002/C182/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	In-vitro diagnostic medical devices — Culture media for microbiology — Performance criteria for culture media	BS EN 12322:1999 (Amendment incorporated)

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CEN EN 13640:2002	OJ2002/C314/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Stability testing of in-vitro diagnostic reagents	BS EN 13640:2002
CEN EN 13641:2002	OJ2002/C314/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Elimination or reduction of risk of infection related to in-vitro diagnostic reagents	BS EN 13641:2002
CEN EN 13975:2003	OJ2003/C280/07 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects	BS EN 13975:2003
CEN EN 14136:2004	OJ2006/C277/04 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures	BS EN 14136:2004

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CEN EN 14254:2004	OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans	BS EN 14254:2004
CEN EN 14820:2004	OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Single-use containers for human venous blood specimen collection	BS EN 14820:2004
CEN EN ISO 14937:2000 Presumption of conformity ceased on 31/04/2010 Superseded by EN ISO 14937:2009 EN ISO 14937:2000/AC:2005	OJ2002/C182/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04	Sterilisation of health care products — General requirements for characterisation of a sterilising agent and the development, validation and routine control of a sterilisation process for medical devices (ISO 14937:2000)	BS EN ISO 14937:2001
CEN EN ISO 14937:2009	OJ2010/C183/04	Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and control of a sterilization process for medical devices (ISO 14937:2009)	BS EN ISO 14937:2009

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CEN EN ISO 15225:2000 EN ISO 15225:2000/A1:2004 EN ISO 15225:2000/A2:2005	OJ2002/C182/06 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000)	BS EN ISO15225:2000
CEN EN ISO 17511:2003	OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)	BS EN ISO 17511:2003
CEN EN ISO 18113-1:2009	OJ2010/C183/04	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)	BS EN ISO 18113- 1:2009
CEN EN ISO 18113-2:2009	OJ2010/C183/04	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)	BS EN ISO 18113- 2:2009
CEN EN ISO 18113-3:2009	OJ2010/C183/04	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)	BS EN ISO 18113- 3:2009

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CEN EN ISO 18113-4:2009	OJ2010/C183/04	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)	BS EN ISO 18113-4:2009
CEN EN ISO 18113-5:2009	OJ2010/C183/04	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009)	BS EN ISO 18113-5:2009
CEN EN ISO 18153:2003	OJ2003/C280/07 OJ2005/C103/03 OJ2005/C240/17 OJ2006/C129/03 OJ2006/C216/03 OJ2006/C277/04 OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials (ISO 18153:2003)	BS EN ISO 18153:2003
CEN EN ISO 20776-1:2006	OJ2007/C186/05 OJ2007/C267/09 OJ2008/C54/07 OJ2008/C186/08 OJ2009/C41/07 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Clinical laboratory testing and in vitro diagnostic test systems - Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases (ISO 20776-1:2006)	BS EN ISO 20776-1:2006
CENELEC EN 61010-2-101:2002	OJ2002/C314/07 OJ2006/C008/09 OJ2008/C304/05 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-101: Particular requirements for in-vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2002 (Modified))	BS EN 61010-2-101:2003

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CENELEC EN 61326-2-6:2006	OJ2008/C304/05 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements — <i>In vitro</i> diagnostic (IVD) medical equipment (IEC 61326-2-6:2005)	BS EN 61326-2-6:2006
CENELEC EN 62304:2006	OJ2008/C304/05 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Medical device software — Software life-cycle processes (IEC 62304:2006)	BS EN 62304:2006
CENELEC EN 62366:2008	OJ2008/C304/05 OJ2009/C95/04 OJ2009/C293/04 OJ2010/C183/04	Medical devices — Application of usability engineering to medical devices (IEC 62366:2007)	BS EN 62366:2008