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EU Publishes New List of Standards Harmonized to the MDD

On August 30, 2012, the European Union published an updated list of standards harmonized to the Medical Device Directive (MDD).

The list identifies the current version of the standard as well as the superseded standard and the date.

This list identifies only the standards marked “new” on the list, except the cases where the new item is a correction or amendment.

New Standard	Prior Version	Date
EN 1865-3:2012 Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher	EN 1865:1999	Dec. 31, 2012
EN 1865-4:2012 Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair	EN 1865:1999	Oct. 31, 2012
EN 1865-5:2012 Patient handling equipment used in road ambulances - Part 5: Stretcher support	EN 1865:1999	Dec. 31, 2012
EN ISO 5359:2008 Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)	EN 739:1998	June 30, 2012
EN ISO 5359:2008/A1:2011	EN 739:1998	June 30, 2012
EN ISO 11137-2:2012 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2012)	EN ISO 11137-2:2007	Sep. 30, 2012
EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)	EN ISO 13485:2003	Aug. 30, 2012
EN ISO 13485:2012/AC:2012		
EN 13727:2012 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)	EN 13727:2003	Nov. 30, 2012
EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	EN ISO 14971:2009	Aug. 30, 2012
EN ISO 25539-1:2009 Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2003 including Amd 1:2005)	EN ISO 25539-1:2008 EN 12006-3:1998+A1:2009	Mar. 21, 2010
EN ISO 25539-1:2009/AC:2011		
EN ISO 25539-2:2009 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2008)	EN ISO 25539-2:2008 EN 12006-3:1998+A1:2009	Mar. 21, 2010
EN ISO 25539-2:2009/AC:2011		

New Standard	Prior Version	Date
EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)	EN 1060-2:1995+A1:2009 EN 1060-1:1995+A2:2009	May 31, 2015
EN 60601-2-33:2002 Medical electrical equipment -- Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2002)	EN 60601-2-33:1995 + A11:1997	Jul, 1, 2005
EN 60601-2-33:2002/A2:2008/AC:2008		
EN 60601-2-52:2010 Medical electrical equipment -- Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009)	EN 60601-2-38:1996 and its amendment + EN 1970:2000	June 1, 2012
EN 60601-2-52:2010/AC:2011		
EN 61217:2012 Radiotherapy equipment - Coordinates, movements and scales (IEC 61217:2011)	EN 61217:1996 and its amendments	Jan. 11, 2015

The URL for the list is <http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices>