



IEC 60601-1 National Harmonized Standards List
**Countries officially accepting IEC 60601-1, Edition 3.1, with* and without modification (not all inclusive)
Edition 3.2 National Standards provided in BLUE, being added as information available (*TBD: To Be Determined*)**


*Countries with no differences are considered covered based on compliance with IEC 60601-1:2005+A1:2012.
Identification of differences is based either on the referenced National/Regional Standard or on the IECCE CB Scheme list of declared differences.
(Where the publisher of a National/Regional Standard identifies their standard as identical (idt) or equivalent (eqv), it is assumed to be identical to IEC 60601-1:2005+A1:2012).*


COUNTRY	STANDARD (Edition 3.1 / Edition 3.2)
Albania	SSH EN 60601-1:2006 + A1:2013 + AC:2014 / TBD
Austria (AU)	ÖVE/ÖNORM EN 60601-1: 2014 02 01 / TBD
Brazil (BR)	NBR IEC 60601-1:2010 + IEC 60601-1:2005/AMD1:2012 / TBD
Bosna Hercegovina	BAS EN 60601-1:2010 + A1:2015 + A12:2016 / TBD
Bulgaria	БДС EN 60601-1:2006 + A1:2013 + AC:2014 / TBD
Canada (CA) *	CAN/CSA C22.2 No. 60601-1:2014 / CAN/CSA-C22.2 NO. 60601-1:14/A2:22
China (CN)	GB 9706.1:2020 / TBD
Denmark (DK)	DS/EN 60601-1:2006 + A1:2013 + AC:2014 / TBD
European Union (EU)	EN 60601-1:2006 + A1:2013 + A12:2014 + AC:2014 / EN 60601-1:2006/A2:2021
Finland (FI)	SFS-EN 60601-1:2007 + A1:2016 / TBD
Former Yugoslav Republic of Macedonia	MCK EN 60601-1:2006 + A1:2016 + AC:2015 / TBD
France (FR)	NF EN 60601-1:2007 + A1:2014 / TBD
Germany (DE)	DIN EN 60601-1:2013; VDE 0750-1:2013-12 / TBD
Hungary (HU)	MSZ EN 60601-1:2017 / TBD
Iceland	IST EN 60601-1:2006 + A1:2013 + AC:2014 / TBD
Ireland	I.S. EN 60601-1:2006 + AMD1:2013 + AMD12:2014 / TBD
Israel *	SI 60601-1 Part 1 / TBD
Japan (JP) *	JIS T 60601-1:2017 / TBD
Korea *	IEC 60601-1:2012 / MDFS No. 2020-12, Annex 1 / TBD
Latvia	LVS EN 60601-1:2007 + A1:2014 / TBD
Lithuania	LST EN 60601-1:2007 + A1:2013 / TBD
Luxembourg	ILNAS-EN 60601-1:2006 + A1:2014 / TBD
Montenegro	MEST EN 60601-1:2010 + A1:2015 + A12:2015 / TBD
Netherlands (NO)	NEN-EN-IEC 60601-1:2006 + A1:2013 + A12:2014 / TBD
Norway (NO)	NEK EN 60601-1:2006 + A1:2013 / TBD
Poland (PL)	PN-EN 60601-1:2011 + A12:2014 AC1:2015 / TBD
Serbia	SPRS EN 60601-1:2012 + A1:2014 + AC:2017 / TBD
Slovenia (SL)	SIST EN 60601-1:2007 + A1:2014 + AC:2015 / TBD
Spain	UNE-EN 60601-1:2008 + A1:2013 + A12:2014 / TBD
Sweden (SE)	SS-EN 60601-1:2006 + A1:2013 + A11:2014 / TBD
Switzerland (CH)	SN EN 60601-1:2010 + A1:2013 + Corr:2014 / TBD
Turkey (TR)	TS EN 60601-1:2007 + A12:2015 + AC:2017 + A12:2017 + A1:2017 / TBD
United States of America (US) *	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (ANSI/AAMI ES60601-1:2005/A1:2012) / ANSI/AAMI ES60601-1:2005/A2:2021
United Kingdom (UK) *	BS EN 60601-1:2006 + A12:2014 / TBD


IEC 60601-1 Base Standard Edition History	
IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Edition 3.2) (2020-08-20) Ed.4 (Project, no date provided)	
<u>History of Editions:</u> (COR: Corrigendum, which are non-technical corrections)	
2020: IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed.3.2)	1995: IEC 601-1:1988/AMD2:1995/COR1:1995 (COR) (Ed.2.2)
2012: IEC 60601-1:2005+AMD1:2012/COR1:2012 (Ed.3.1)	1995: IEC 601-1:1988/AMD2:1995 (Ed.2.2)
2012: IEC 60601-1:2005+AMD1:2012 (Ed.3.1)	1991: IEC 601-1:1988/AMD1:1991 (Ed.2.1)
2005: IEC 60601-1:2005/COR2 (Ed.3.0)	1988: IEC 601-1:1988 (Ed.2)
2005: IEC 60601-1:2005/COR1 (Ed.3.0)	1984: IEC 601-1:1977/AMD1:1984 (Ed.1.1)
2005: IEC 60601-1:2005 (Ed.3.0)	1977: IEC 601-1:1977 (Ed.1)
1997: IEC 60601-1:1988/AMD2:1995 (Ed.2.2) (IEC added "60" to front)	

USA  FDA Regulatory Submittals - National Standard Editions & History	
ANSI/AAMI ES60601-1:2005/A2:2021 (2022-02-01) (IEC Ed.3.2) [2023-12-17]	
ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (2012-08-17) (IEC Ed.3.1) [Transition Period]	
NRTL Safety Marks: IEC/AAMI Editions 3, 3.1, 3.2 (Edition 2, UL 60601-1, UL 2601-1 No Longer Accepted by OSHA)	
<u>History of Editions:</u>	
2022: ANSI/AAMI ES60601-1:2005/A2:2021 (IEC Ed.3.2)	
2012: ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (IEC Ed.3.1) = ANSI/AAMI ES60601-1:2005/A1:2012	
2012: ANSI/AAMI ES60601-1:2005/(R)2012 (IEC Ed.3.1)	
2005: ANSI/AAMI ES60601-1:2005 (IEC Ed.3.0)	
2003: UL 60601-1 (IEC Ed.2.2)	
1997: UL2601-1, Ed.2 (IEC Ed.2.2)	
1994: UL 2601-1, Ed.1 (IEC Ed.2.0)	
1972: UL 544 (Medical & Dental); UL 187 (X-Ray Equipment)	














CANADA  Health Canada Regulatory Submittals - National Standard Editions & History	
CAN/CSA-C22.2 NO. 60601-1:14/A2:22 (2022-03-01) (IEC Ed.3.2) [~2025-03-01]	
CAN/CSA-C22.2 No. 60601-1:14 (2014-03-01) (IEC Ed.3.1) [Transition Period]	
SCC Safety Marks: IEC/CSA Editions 3.0, 3.1, 3.2	
<u>History of Editions:</u>	
2022: CAN/CSA-C22.2 NO. 60601-1:14/A2:22 (IEC Ed.3.2)	
2014: CAN/CSA-C22.2 No. 60601-1:14 (IEC Ed.3.1)	
2008: CAN/CSA C22.2 No. 60601-1:08 (IEC Ed.3.0)	
1990: CAN/CSA C22.2 No.601.1-M90 (IEC Ed.2.2)	
1990: CAN/CSA-C22.2 No.114-M90 (Diagnostic Imaging & Radiation Therapy Equip.)	
1984: CAN/CSA C22.2 No. 125-M1984 (Electromedical Equipment)	

EUROPEAN UNION  Notified Body Regulatory Submittals (MDR) - National Standard Editions & History	
EN 60601-1:2006/A2:2021 (2021-10-08) (IEC Ed.3.2) [2024-10-08]	
EN 60601-1:2006/A1:2013 (2013-10-03) (IEC Ed.3.1) + A.12:2014 (2014-10-02) [Transition Period]	
CE Marking Medical Devices:	
Medical Device Regulation (MDR): [Required for ALL new devices, May 25, 2024 for devices already on market] (conditional)	
Medical Device Directive (MDD): [Expired for new devices, until May 25, 2024 for devices already on market] (conditional)	
<u>History of Editions:</u>	
2022: EN 60601-1:2006/A2:2021 (IEC Ed.3.2)	
2014: EN 60601-1:2006/A1:2013 + EU AMD12:2014 (IEC Ed.3.1)	
2013: EN 60601-1:2006/A1:2013 (IEC Ed.3.1)	
2006: EN 60601-1:2006 (IEC Ed.3.0)	
1995: EN 60601-1:1990/A2:1995 (IEC Ed.2.2)	
1993: EN 60601-1:1990/A1:1993 (IEC Ed.2.1)	

JAPAN  Regulatory Submittals - National Standard Editions & History
JIS T 60601-1:2012 + A1:2014 (2014-11-02) (IEC Ed.3.1) [Required]
History of Editions:
2014: JIS T 60601-1:2012 + AMD1:2014 (IEC Ed.3.1)
2012: JIS T 60601-1:2012 (IEC Ed.3.0)

REPUBLIC OF KOREA  KFDA Regulatory Submittals - National Standard Editions & History
KS C IEC 60601-1:2011 (2011-12-08) (IEC Ed. 3.1 + Korea Differences) [Required] (Requires <u>In-Country Testing</u> or a <u>CB Report/Certificate</u> to get In-Country Issued Report for Regulatory Submission) (Notification of MFDS No.2020-12, Annex 1: <u>110/220/380V, 60Hz, KSC 8305 and 8300 mains plugs, Korean language IFU and markings</u>)
History of Editions:
2011: KS C IEC 60601-1:2011 (IEC Ed.3.1)

CHINA  Regulatory Submittals - National Standard Editions & History
GB 9706.1-2020 (2020-04-09), (IEC Ed.3.1) (IEC 60601-1, Edition 3.1 + China Differences) [Required] (Requires <u>In-Country Testing of ALL Devices</u> , no exclusion with CB Report/Certificate)
History of Editions:
2020: GB 9706.1-2020 (IEC Ed.3.1)
2008: GB 9706.1-2007 (IEC Ed. 2.2)
1996: GB 9706.1-1995 (IEC Ed. 2.1)
1985: GB 9706.1-88 (IEC Ed1.1)

USA OSHA list of NRTLs (safety marks) with ANSI/AAMI ES 60601-1 Accreditation for Medical Electrical Equipment		
OSHA Nationally Recognized Testing Laboratories Marks, Names, Locations Under standards ANSI/AAMI ES60601-1 (Edition 3.0, 3.1, 3.2) accepted (Edition 2, UL 60601-1, UL 2601-1 no longer recognized)		
Mark	NRTL Name	NRTL Specified Location(s)
	<u>Bureau Veritas Consumer Products Services, Inc. (BVCPS)</u>	USA (MA), Taiwan, China
	<u>CSA Group Testing and Certification Inc.</u>	USA (CA, GA, TX), Canada, United Kingdom, Germany, The Netherlands, India, Italy, Republic of Korea, Japan, Taiwan, China
	<u>DEKRA Certification, Inc.</u>	USA (VA), The Netherlands
	<u>Element Materials Technology Portland – Evergreen Inc.</u>	USA (CA)
	<u>Eurofins Electrical and Electronic Testing NA, Inc.</u>	USA (MD)
	<u>Intertek Testing Services NA, Inc.</u>	USA (WI, MN, IL, NY, NJ, TX, GA, CA, MA, MI, OH, CA), Canada, Germany, Hong Kong, India, Italy, Japan, Mexico, South Korea, Sweden, Taiwan, Thailand, United Kingdom, China
	<u>Nemko North America, Inc.</u>	USA (CA), Canada
	<u>QAI Laboratories, LTD (QAI)</u>	USA (CA), Canada
	<u>QPS Evaluation Services Inc.</u>	Canada
	<u>SGS North America, Inc.</u>	USA (GA), China, Spain, United Kingdom, France, Finland
	<u>TUV Rheinland of North America, Inc.</u>	USA (MA, NY, CT, CA), Japan, Germany, Taiwan, China
	<u>TÜV SÜD America Inc.</u>	USA (MA, MN, FL, CA), Canada, Germany, Tokyo, South Korea, Singapore, Taiwan, United Kingdom, China
	<u>UL Underwriters Laboratories Inc.</u>	USA (IL, MI, MN, NY, NC, TX, WA, CA), Brazil, Canada, Germany, Denmark, France, Hong Kong, India, Italy, Japan, South Korea, Malaysia, Mexico, New Zealand, Poland, Singapore, Spain, Taiwan, Thailand, Turkey, United Arab Emirates, United Kingdom, China