

Medical - 60601-1 (Ed. 3.2rd)

Market	Standard	DOP Date of publication	Note
IECEE	IEC 60601-1:2005+A1:2012+A2:2020	2020/08/20	Edition 3.2 includes ISO 14971:2019 (the latest version) : "Medical devices—Application of risk management to medical devices,"
EU & UK	EN 60601-1:2006+A1:2013+A2:2021	2022/04/08	Date of withdrawal (dow): 2024/10/08 Edition 3.2 is not accepted by the European Commission yet, but CENELEC (EU' s Certification Body) is expected to harmonize 60601-1 Ed 3.2 with the new EU Medical Device Regulation' s General Safety and Performance Requirements (GSPR) by 2024/5/27.
US	ANSI/AAMI ES60601-1:2005+A1:2012+A2:2021	FDA: recognized on 2022/5/30	FDA will accept the declarations of conformity of ANSI/AAMI ES60601-1:2005+A1:2012+A2:2021 Ed 3.1 by 2023/12/17. After this transition period, declarations of conformity of ANSI/AAMI ES60601-1:2005+A1:2012+A2:2021 Ed 3.1 will not be accepted ANSI/AAMI ES60601-1:2005+A1:2012+A2:2021 Ed 3.1 will be replaced by Edition 3.2 .
Canada	CAN/CSA C22.2 No. 60601-1:14+A2:22	2022	N/A