

2024.H1 Safety Regulation Update for MW certificate

Category	EU Standard	US Standard	Status for MW certificate
Medical	EN 60601-1:2006+A2:2021 Mandatory 2024-10-08	ANSI/AAMI ES60601-1: 2005+A2:2021 Mandatory 2023-12-17	1. TUV & UL certificate is complete 2. CB for GST/MST is complete 3. CB for RPS will be completed by 4/E
	EN 60601-1-11:2015+A1:2021 Mandatory 2024-07-16	EN 60601-1-11:2015+A1:2021 Mandatory 2024-07-16	had completed
LED	EN 61347-1:2015+A1:2021 Mandatory EU OJ (Official Journal) : N/A Cenelec : 2024-01-08	N/A	had completed
Household	EN 60335-1:2012+A15:2021 EN IEC 60335-1:2022 Mandatory 2024-03-01	N/A	had completed
	EN 60335-2-29:2021+A1:2021 Mandatory 2024-11-15	N/A	had completed
	EN IEC 60335-2-89:2022 Mandatory 2024-05-04	N/A	BY product only for EUMW

ED	IEC (International Standard) - CB	EN (EU Standard)	UL (US Standard)
ED.1	IEC 62368-1:2010 Had abolished by IEC	N/A Has not been adopted by EU OJ (Official Journal)	UL 62368-1:2012 (Not mandatory)
ED.2	IEC 62368-1:2014	EN 62368-1:2014+A11:2017 Mandatory by OJ : 2019-12-14	UL 62368-1:2014 Mandatory : 2019-12-14
ED.3	IEC 62368-1:2018 Most countries currently accept	EN IEC 62368-1:2020+A11:2020 The latest EU standards EU OJ Mandatory day: N/A Cenelec indicative : 2024-07-06 Has not been adopted by EU OJ (Official Journal)	UL 62368-1:2021 The latest US standards The new product is mandatory by 2024.07.06
ED.4	IEC 62368-1:2023 2023.05.26 Published Only US/CANADA/JAPAN NATIONAL DIFFERENCE	Estimate 2024 2H Publish	Estimate 2024 2H Publish

Standard	IEC (International Standard) - CB	had completed	had completed
		EN (EU Standard)	ANSI/AAMI (US Standard)
Part 1	IEC 60601-1:2005+A1:2012 (3.1)	EN 60601-1:2006+A11+A1+A12:2014	ANSI/AAMI ES60601-1: 2005+A1:2012
	IEC 60601-1:2005+A2:2020 (3.2) General requirements for basic safety and essential performance	EN 60601-1:2006+A2:2021 (Mandatory) MDR: Estimated time 2024-10-08 Cenelec: 2024-10-08	ANSI/AAMI ES60601-1: 2005+A2:2021 (Mandatory) FDA: 2023-12-17
Part 11	IEC 60601-1-11:2015 (2.0)	EN 60601-1-11:2015	ANSI/AAMI HA60601-1-11:2015
	IEC 60601-1-11:2015+A1:2020 (2.1) Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	EN 60601-1-11:2015+A1:2021 (Mandatory) Cenelec: 2024-07-16	ANSI/AAMI HA60601-1-11:2015/A1:2021

Status:

1. TUV & UL certificate is complete
2. CB for GST/MST is complete
3. **CB for RPS will be completed by 4/E**

Regulation update status – LED – IEC/EN 61347

had completed

had completed

Standard	IEC (International Standard) - CB	EN (EU Standard)
Part 1	IEC 61347-1:2015 (3.0)	EN 61347-1:2015
	IEC 61347-1:2015+A1:2017 (3.1) Lamp controlgear	EN 61347-1:2015+A1:2021 (Mandatory) EU OJ (Official Journal) : N/A Cenelec : 2024-01-08
Part 11	IEC 61347-2-11:2001+A1:2017 (1.1) —————> DAP-04 Miscellaneous electronic circuits used with luminaires	EN 61347-2-11:2001+A1:2019 (Mandatory) EU OJ (Official Journal) : N/A Cenelec : 2022-06-14
Part 13	IEC 61347-2-13:2014+A1:2016 (2.1) DC or AC supplied electronic controlgear for LED modules	EN 61347-2-13:2014+A1:2017
Performance (ENEC)	IEC 62384:2020 (2.0) DC or AC supplied electronic control gear for LED modules – Performance requirements	EN IEC 62384-1:2020 (Mandatory) Cenelec : 2023-06-17

Standard	IEC (International Standard) - CB	EN (EU Standard)
Part 1	<p>IEC 60335-1:2010+A1:2013+A2:2016 (5.2) Household and similar electrical</p>	<p>EN 60335-1:2012+A15:2021 EN IEC 60335-1:2022</p> <p>had completed</p> <p>(Withdrawal) EU OJ (Official Journal) : 2023-06-21 Cenelec : 2024-03-01</p>
Part 2-29	<p>IEC 60335-2-29:2016+A1:2019 (5.1) Battery chargers</p>	<p>EN 60335-2-29:2021+A1:2021</p> <p>had completed</p> <p>(Withdrawal) EU OJ (Official Journal) : 2023-11-10 Cenelec : 2024-11-15</p>
Part 2-89	<p>IEC 60335-2-89:2019 (3.0) Commercial refrigerating appliances with an incorporated or remote refrigerant condensing unit or compressor</p>	<p>EN IEC 60335-2-89:2022 → BY product for EUMW</p> <p>(Withdrawal) EU OJ (Official Journal) : N/A Cenelec indicative : 2024-05-04</p>