

mSafety regulatory compliance

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Medical device, worldwide	Contact allergy standard, worldwide
IEC 60601-1-1: Safety	ISO10993-5: Cytotoxicity Test
IEC 60601-1-2: EMC	ISO10993-10: Skin Irritation Test
IEC 60601-1-11: Home healthcare environment	ISO10993-10: Skin Sensitization Study (Maximization Test)

TA	Region	Standards	Description
CE	Europe	EN 50566	Health: RED Art 3.1a: Exposure (EMF)
CE	Europe	EN 50663	Health: RED Art 3.1a: Human Exposure (EMF)
CE	Europe	EN 60950-1 + A1 + A2 + A11 + A12	Safety: RED Art 3.1a: Obsolete for EU, replaced by EN62368
CE	Europe	EN 62368-1 + A11	Safety: RED Art 3.1a
CE	Europe	Draft EN 301 489-1	EMC: RED Art 3.1b
CE	Europe	EN 301 489-3	EMC: RED Art 3.1b: NFC
CE	Europe	Draft EN 301 489-17	EMC: RED Art 3.1b: BT/WLAN
CE	Europe	EN 301 489-19	EMC: RED Art 3.1b: GNSS
CE	Europe	Draft EN 301 489-52	EMC: RED Art 3.1b: LTE
CE	Europe	EN 300 328	Radio Spectrum: RED Art 3.2: BLE/WLAN
CE	Europe	EN 301 908-1	Radio Spectrum: RED Art 3.2: LTE
CE	Europe	EN 300 330	Radio Spectrum: RED Art 3.2: NFC
CE	Europe	EN 303 413	Radio Spectrum: RED Art 3.2: GNSS
CE	Europe	EN 301 908-13	Radio Spectrum: RED Art 3.2: LTE
CE	Europe	EN 50581	RoHS
FCC	US	FCC 15B	LTE
FCC	US	FCC 15C	NFC/BLE
FCC	US	FCC 27	LTE
FCC	US	FCC 90	LTE
IC	CAN	IC RSS-130	LTE
IC	CAN	IC RSS-139	LTE
IC	CAN	IC RSS-140	LTE
IC	CAN	IC RSS-210	NFC
IC	CAN	IC RSS-247	BLE
JATE	Japan		Telecommunications equipment compliance
TELEC	Japan		Radio equipment compliance