



Eterna™

Charger

REF 16000



IP22

ETL CLASSIFIED



Intertek
4009322



Abbott Medical

6901 Preston Road
Plano TX 75024
USA

FCC ID: PX2-GMCHG1

Label_PN
ZFIN_PN

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	CLASS II ME EQUIPMENT, externally powered		Pass
	INTERNALLY POWERED ME EQUIPMENT		Pass
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		Pass
	TYPE B APPLIED PART	TYPE BF APPLIED PART	N/A
	TYPE BF APPLIED PART		Pass
	TYPE CF APPLIED PART		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529.....:	Rated IP22	Pass
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use.....:	Not intended to be sterilized	N/A
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2	Not intended for use in an OXYGEN RICH ENVIRONMENT	N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION.....:	CONTINUOUS OPERATION	Pass
7	ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS		
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6.....:	See Appended Table 7.1.2	Pass
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	See appended Tables 7.1.3 and 8.10	Pass
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		Pass
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings.....:	See attached copy of Marking Plate	Pass
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS.....:	Equipment marked	N/A
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	Equipment marked	N/A
	Single use item marked.....:	Adhesive patch marked single use	Pass
7.2.2	ME EQUIPMENT marked with:		Pass
	– the name or trademark and contact information of the MANUFACTURER		Pass
	– a MODEL OR TYPE REFERENCE	See attached copy of Marking Plate	Pass
	– a serial number or lot or batch identifier; and	Etched on the device and also included on the package markings	Pass
	– the date of manufacture or use by date		N/A
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	USB Cable considered. Misidentification does not present an unacceptable RISK.	Pass