

Sub Product Category - Electrocardiography EKG units & related products UNSPSC CODE 421817

Product category - Electrocardiography EKG units UNSPSC CODE 42181701 ITC-HS Code : 90181100

(*Demand aggregation to be done on UNSPSC code)

S No.	Parameters		Value 1	Remarks	Priority	unit	Validation
1	GMDN name and Code	CH	Multichannel Electrocardiographic , CT-1115				
2	Functional requirements: electricity (AC-powered) bedside device designed to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient, it also typically display heart rate. The device is typically equipped with audible and/or visual alarms that are triggered when the patient's parameters drop below or exceed pre-set limits. Continuous display of patient ECG and heart rate on screen,Allows display of single, 5 lead ECG or simultaneous display of at least 5 waves selected from up to 12 points.Operator can set audiovisual alarm levels for low or high heart rate.Operates from mains voltage or from internal rechargeable battery.	CH	yes				
3	Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm	CH	yes				
4	Heart rate trend display of at least previous 24 hours	Ch	yes				
5	Arrhythmia detection facility required; minimum gradation of 1 bpm	N	yes				
6	Audiovisual alarms required: high and low heart rate (operator variable settings), cardiac arrhythmia, sensor / wire disconnected, low battery	CH	yes				
7	User's interface		manual				
8	In built Software and/or standard of communication		yes				
9	weight	N		must declare		gram	≤ 5000
10	Mobility, portability	CH	Protective splashproof case for clean storage and safe transport				
11	Display must allow easy viewing in all ambient light levels	Ch	yes				
12	Noise Level	N		must declare		dba	≤ 50

13	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a exhaust cooling fan	Ch	yes				
14	power input and frequency	CH	220 to 240V, 50 Hz				
15	Power consumption	N		must declare		watt	
16	Power cable length	N	3			meter	
17	Electrical protection provided by fuses in both live and neutral supply lines.	CH	yes				
18	Operating condition:Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances	CH	yes				
19	STANDARDS AND SAFETY:FDA / CE approved product; Manufacturer / supplier should have ISO 13485 certificate for quality standard. Electrical safety conforms to standards for electrical safety IEC-60601-1 Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility) and IEC 60601-2-25 (essential performance of electrocardiographs)	CH	yes				
20	Warranty	CH	3 years warranty & one year with min. 3 free servicing.				
21	Others: List of important spare parts and accessories with their part number and costing. Certificate of Callibration and Inspection to be provided	CH	YES				
	Approved By		Moderated By	Prepared By			
	(Sh.P.SINGHAL)DDG(Q.A.)(H.QRS)		(Sh.A.K.MI.KASHYAP)DD(Q.A.)	(s k shukla)AD(QA)-II			
			(Sh.S.K.AGRAWAL)D(QA)				