

FILE No.																	
Creator : Mr. Firoj Technical Assistant				Moderator : Shri A.V.Muralidharan (Dy. CEO GeM)						Approver : A K Kamra							
Superlative Category :																	
Major Category :																	
Sub Category :																	
ECG Machine : UNSPSC Code																	
S.No.	Parameters			Value 1	Value2	Value 3	Value 4	Value 5	Value 6	Value 7	Value 8	Validation	Golden parameter	Remarks	P r i o r	U n i t	Demand Aggregation
Certificates																	
1	Confirmity to standards	S	Enumerable	US FDA	European CE	Both US FDA AND CE	BIS						G				
2	Confirmity to safety of electromagnetic compatibility	S	Enumerable	IEC-60601-1-2:2001 (or equivalent BIS)													
3	Confirmity to safety of Eletrocardiograms			IEC-60601-2-25													
4	Confirmity to medical electrical safety standards	S	Enumerable	IEC60601-1-2005													
5	Confirmity to manufactures certification	S	Enumerable	ISO 9001 & ISO 13485									G				
General Parameters																	
6	Purpose	P	Enumerable	ECG machine is primary equipment to record ECG signal with interpretation which is required for recording and analyzing the waveforms with software.									G				
7	Operating modes of ECG Machine	P	Enumerable	Automatic, Manual and Rhythm													
8	ECG machine should have ECG lead annotation facility	P	Enumerable	Yes									G				
9	Leads which is in ECG machine should be able to acquire simultaneously and interpret them	P	Enumerable	12									G				
10	Number of channels	P	Enumerable	3	12								G				

