

Level 1 Category : Medical Equipment and Accessories and Supplies - UNSPS Code 42000000

Level 2 Category : Surgical Products - UNSPS Code 42290000

Level 3 Category : Endoscopes - UNSPS Code 42296300

Level 4 Category : Video Endoscope Unit Having Sigmoidoscope - UNSPS Code 42296397

DRAFT  
T/P Post CCM

GEM Version 3.0

S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES (in drop down box for selection of values from the options if	UNIT	CATEGORY OF FIELD	REMARKS
<b>GENERAL FEATURES</b>							
1	Product description	--	ENUMERABLE	Video Endoscope Unit Having Sigmoidoscope	--	MANDATORY	
2	Clinical purpose	--	ENUMERABLE	To examine large intestine from the rectum through the nearest part of the colon i.e sigmoid colon	--	MANDATORY	
3	Items Included	--	ENUMERABLE	Sigmoidoscope, Video Processor, Computer System with High Definition Medical Grade Monitor(compatible with the scope), Printer, Trolley , endoscopic software and Standard Accessories	--	MANDATORY	
<b>SIGMOIDOSCOPE SPECIFICATIONS</b>							
1	Conformity to Standard	--	ENUMERABLE	IS 15732 (Part 1)/ISO 8600-1 : Latest Revision	--	MANDATORY	
3	Sigmoidoscope should be fully immerssible in disinfectant solution with or without resistant cap	--	ENUMERABLE	Yes	--	MANDATORY	
4	Inbiult Image sensor type	--	ENUMERABLE	CCD / CMOS	--	MANDATORY	
5	Image sensor should be HDTV Compatible	--	ENUMERABLE	Yes	--	MANDATORY	
6	Provision of near/close focus observation	--	ENUMERABLE	Yes	No	--	GOLDEN PARAMETER
7	Provision of inbuilt identification memory chip for monitor display of scope model no. , serial no, white balancing memory, No of connections	--	ENUMERABLE	Yes	--	MANDATORY	
8	Provision of forward/auxillary water jet for mucosal cleaning	--	ENUMERABLE	Yes	--	MANDATORY	
9	Field of view/ Angle of view for Normal/Near Focus	Must Declare	MEASURABLE	140 - 200	degree	--	GOLDEN PARAMETER
10	Direction of view	--	ENUMERABLE	Forward viewing	--	MANDATORY	
11	The field of view and direction of view of sigmoidoscope shall be tested and determined in accordance with ISO 8600-3 (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes	--	MANDATORY	
12	Depth of Field	--	ENUMERABLE	2-3 mm to 100 mm	--	MANDATORY	
13	Distal end outer Diameter	Must Declare	MEASURABLE	8-13	mm	--	GOLDEN PARAMETER
14	Insertion tube outer diameter	Must Declare	MEASURABLE	8-13	mm	--	GOLDEN PARAMETER
15	The maximum insertion portion width shall be tested and determined in accordance with ISO 8600-4 (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes	--	MANDATORY	
16	Instrument channel inner diameter	--	ENUMERABLE	3.4 or more	--	MANDATORY	
17	Working Length	Must Declare	MEASURABLE	630 -800	mm	--	GOLDEN PARAMETER

18	Total Length	Must Declare	MEASURABLE	1000 -1400			mm	GOLDEN PARAMETER	
19	Minimum Visible Distance	--	ENUMERABLE	3.0 mm or closer from the distal end			--	MANDATORY	
20	Minimum tip bending range	--	ENUMERABLE	up 180 deg, Down 180 deg, Right 160 deg, Left 160 deg			--	MANDATORY	
21	The surface of the Sigmoidoscope shall be free of pores, cracks, and remainders of tooling agents	--	ENUMERABLE	Yes			--	MANDATORY	
22	Materials used for the outer surface of the insertion portion shall be evaluated for biological compatibility in accordance with ISO 10993-1(Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes			--	MANDATORY	
23	A risk management procedure shall be carried out by manufacturer in accordance with ISO 14971 to consider the probability of disconnection of medical devices intended for connection to endoscopes or endotherapy devices to non-endoscopic patient connections (e.g. intravenous applications)	--	ENUMERABLE	Yes			--	MANDATORY	
<b>VIDEO PROCESSOR SPECIFICATIONS</b>									
1	Video Processor should be compatible with the sigmoidoscope	--	ENUMERABLE	Yes			--	MANDATORY	
2	Video processor should be compatible with digital HD-SDI/ DVI output for HDTV monitor and should contain electronics for clear visibility of near and far objects	--	ENUMERABLE	Yes			--	MANDATORY	
3	Provision of RGB, S-video, composite video output function	--	ENUMERABLE	Yes			--	MANDATORY	
4	Equipped With high resolution HDTV imaging capacity (1080 P)	--	ENUMERABLE	Yes			--	MANDATORY	
5	Provision of chromo endoscopy imaging	--	ENUMERABLE	Yes			--	MANDATORY	
6	Provision of Portable memory and USB slot for still image recording	--	ENUMERABLE	Yes			--	MANDATORY	
7	Provision of automatic IRIS control and white balance	--	ENUMERABLE	Yes			--	MANDATORY	
8	Provision of Picture in picture display and index function ability	--	ENUMERABLE	Yes			--	MANDATORY	
9	Provision of Electronic Zoom upto	--	ENUMERABLE	1.5 X	2 X		--	GOLDEN PARAMETER	
10	Equipped with memory backup for settings and lithium battery	--	ENUMERABLE	Yes			--	MANDATORY	
11	Provision of prefreeze function for image stabilization	--	ENUMERABLE	Yes			--	MANDATORY	
12	Provision of Light Source	--	ENUMERABLE	In-built	Separate		--	GOLDEN PARAMETER	
13	Light Source Type	--	ENUMERABLE	Xenon lamp	LED Lamp		--	GOLDEN PARAMETER	
14	Power of Lamp	--	MEASURABLE	300			Watt	MANDATORY	
15	Provision of Stanby/Emergency Lamp of equal rating	--	ENUMERABLE	Yes for Xenon Lamp	NA for LED		--	GOLDEN PARAMETER	
16	Minimum Average lamp life	--	ENUMERABLE	500 hours of continuous use for Xenon lamp	5000 hours of continuous use for LED Lamp		--	GOLDEN PARAMETER	

17	Provision for lamp switch over from main lamp to stand by lamp in case of main lamp failure	--	ENUMERABLE	Yes			--	MANDATORY	
18	Provision of backlit front panel indicator	--	ENUMERABLE	Yes			--	MANDATORY	
19	Equipped with automatic light adjustment facility	--	ENUMERABLE	Yes			--	MANDATORY	
20	Cooling Method	--	ENUMERABLE	Forced air cooling			--	MANDATORY	
21	Equipped with regulated air feeding pump and fan with low noise	--	ENUMERABLE	Yes			--	MANDATORY	
22	Video processor should be supplied with minimum 2 KW online UPS	--	ENUMERABLE	Yes			--	MANDATORY	
23	Provided with two water bottles compatible with processor	--	ENUMERABLE	Yes			--	MANDATORY	

#### MONITOR SPECIFICATIONS

1	Monitor should be compatible with the scope	--	ENUMERABLE	Yes			--	MANDATORY	
2	Monitor should be high definition medical grade	--	ENUMERABLE	Yes			--	MANDATORY	
3	Type of Monitor	--	ENUMERABLE	Color LCD	Color LED		--	GOLDEN PARAMETER	
4	Size of Monitor	Must Declare	MEASURABLE	24-32			inch	GOLDEN PARAMETER	
5	Monitor should have aspect ratio of 16:9/16:10 with output of (1080/601:NTSC) (1080/501:PAL)	--	ENUMERABLE	Yes				MANDATORY	
6	Monitor should have provision of accepting HD-SDI and DVID signal	--	ENUMERABLE	Yes			--	MANDATORY	
7	Monitor should have low power consumption	--	ENUMERABLE	Yes			--	MANDATORY	
8	Provision of picture in picture and picture out picture for viewing side by side split screen images	--	ENUMERABLE	Yes			--	MANDATORY	
9	Monitor should have wide viewing angle	--	ENUMERABLE	Yes			--	MANDATORY	

#### COMPUTER SYSTEM SPECIFICATIONS

1	Processor	--	ENUMERABLE	core i3	core i5	core i7	--	GOLDEN PARAMETER	
2	Operating System	--	ENUMERABLE	Windows			--	MANDATORY	
3	RAM Size	--	ENUMERABLE	4 GB	8 GB	16 GB	--	GOLDEN PARAMETER	
4	Hard Disk Capacity	--	ENUMERABLE	500 GB	1 TB		--	GOLDEN PARAMETER	

#### ENDOSCOPIC SOFTWARE SPECIFICATIONS

1	High Definition Patient reporting software to record and capture the still images during the procedure should be provided with the unit	--	ENUMERABLE	Yes			--	MANDATORY	
2	Provision of Foot switch and image capture dongle along with the software	--	ENUMERABLE	Yes	No		--	GOLDEN PARAMETER	
3	Image capture software should be compatible with the computer system and Printer provided	--	ENUMERABLE	Yes			--	MANDATORY	

#### PRINTER SPECIFICATIONS

1	Printing Technology	--	ENUMERABLE	Laser			--	MANDATORY	
2	Type of Printer	--	ENUMERABLE	Color			--	MANDATORY	
3	USB connectivity in Printer	--	ENUMERABLE	Yes			--	MANDATORY	

TROLLEY SPECIFICATIONS									
1	Material of Trolley	--	ENUMERABLE	Stainless Steel 304 Grade			--	MANDATORY	
2	Trolley should have space to accommodate the video processor, monitor and all the required equipments	--	ENUMERABLE	Yes			--	MANDATORY	
3	Provision of Scope hanger in the trolley to hold the scope during the procedure	--	ENUMERABLE	Yes			--	MANDATORY	
4	Trolley should be powder coated good quality rust free and should be able to take load of minimum up to 70 Kg	--	ENUMERABLE	Yes			--	MANDATORY	
5	Trolley should have antistatic castor wheels having front locking facility to move the trolley	--	ENUMERABLE	Yes			--	MANDATORY	
STANDARD ACCESSORIES									
1	Reusable Biopsy Forcep oval cup fenestrated	--	NUMERIC	2			Nos	MANDATORY	
2	Reusable Biopsy Forcep oval cup non fenestrated	--	NUMERIC	2			Nos	MANDATORY	
3	Channel Cleaning Brushes	--	NUMERIC	5			Nos	MANDATORY	
4	Channel Opening Brushes	--	NUMERIC	5			Nos	MANDATORY	
5	Washing Pipe/Spray Catheter	--	NUMERIC	10	Not Provided		Nos	GOLDEN PARAMETER	
6	Injection needle (21 G)	--	NUMERIC	10			Nos	MANDATORY	
7	Grasping Forcep - rat tooth	--	NUMERIC	2	Not Provided		Nos	GOLDEN PARAMETER	
8	Biopsy channel valves	--	EMUMERABLE	5 pack of 10 each	Not Provided		--	GOLDEN PARAMETER	
9	Reusable Extra suction and air water buttons	--	ENUMERABLE	5 each	Not Provided		--	GOLDEN PARAMETER	
10	All the accessories provided should be compatible with the Sigmoidoscope and authorization certificate for compatibility by the parent company/supplier of the sigmoidoscope should be provided	--	ENUMERABLE	Yes			--	MANDATORY	
ELECTRICAL REQUIREMENTS									
1	Input Power Supply	--	ENUMRABLE	220-240V AC, 50 HZ fitted with 3 pin Indian plug of appropriate rating			--	MANDATORY	
ENVIRONMENTAL CONSIDERATIONS									
1	Operating Conditions	--	ENUMRABLE	10 deg C to 40 deg C, RH 15% to 90%			--	MANDATORY	
2	Storage conditions	--	ENUMRABLE	0 deg C to 50 deg C, RH 15% to 90%			--	MANDATORY	
PACKING MODE									
1	The complete unit should be packed including all the accessories in such a way that there is no transit damage takes place during transportation till destination	--	ENUMERABLE	Yes			--	MANDATORY	
CERTIFICATIONS & REPORTS									
1	Submission of Test Report/Quality Control Report to the buyer from parent manufacturer complying that the product meets the defined set of declared specifications	--	ENUMRABLE	Yes			--	MANDATORY	
2	Product Certifications (Proof of the same to be submitted to buyer)	--	ENUMERABLE	BIS	EU-CE	US-FDA	--	GOLDEN PARAMETER	Multi Select

3	Four digit number of notified body if product is EU-CE certified	Write '0' if not applicable	NUMERIC				--	MANDATORY	AKBNV
4	Certificate No	Must Declare	TEXT				--	MANDATORY	AKBNV
5	Certificate Date	Must Declare	TEXT				--	MANDATORY	AKBNV
6	Certificate Issuing Authority	Must Declare	TEXT				--	MANDATORY	AKBNV
7	ISO 13485 Certified Manufacturer (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes			--	MANDATORY	
8	Sigmoidoscope shall conform to IEC 60601-2-18 for safety and essential performance requirements (Proof of the same to be submitted to buyer on demand)	--	EMUMERABLE	Yes			--	MANDATORY	
9	Certification, performance and safety standards specific to the whole unit (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	IEC 60601-1	IS:13450(Part 1)		--	MANDATORY, FILTER	Multiselect
<b>INSTALLATION &amp; TRAINING</b>									
1	Supplier to perform installation, demonstration, safety and operation checks before handover	--	ENUMERABLE	Yes			--	MANDATORY	
2	Onsite operational as well as general troubleshooting User level maintenance training shall be given to the user during supply and as when required by the user	--	ENUMERABLE	Yes			--	MANDATORY	
<b>WARRANTY &amp; MAINTENANCE</b>									
1	On site Warranty (Year)	--	NUMERIC	5			Year	MANDATORY	
2	User technical and maintenance manual detailing complete maintaining schedule with routine maintenance should be provided	--	ENUMERABLE	Yes			--	MANDATORY	
3	After sale support service facility to the user	--	ENUMERABLE	Yes			--	MANDATORY	
4	Contact details of manufacturer, supplier and local service agent to be provided	--	ENUMERABLE	Yes			--	MANDATORY	

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