

File No.GEM/TP/Retinal/Fundus Camera/2018 (Version 3.0)											Draft T/P		
Level 1 Category: Medical Equipment and Accessories and Supplies -UNSPS Code 42000000													
Level 2 Category: Patient exam and monitoring products - UNSPS Code 42180000													
Level 3 Category: Ophthalmic cameras -UNSPS Code 42183400													
Level 4 Category: Retinal Camera or Fundus Camera for Eye Neonatal Screening-(RBSK) -UNSPS Code 42183403											GEM Version 3.0		
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES							UNIT	CATEGORY OF FIELD	REMARKS
<b>GENERAL FEATURES</b>													
1	Product	--	ENUMERABLE	Digital Retinal Camera or Digital Fundus camera for neonatal eye screening							--	MANDATORY	
2	Type	--	ENUMERABLE	Hand held and portable							--	MANDATORY	
3	Purpose	--	ENUMERABLE	To illuminate and image the retina simultaneously and to report the birth prevalence, risk factors, characteristics and location of fundus hemorrhages (FH) of the retina and optic nerve present in newborns at birth for early detection and treatment of eye diseases, which may in turn help to preserve visual function and prevent blindness							--	MANDATORY	
	Application	--	ENUMERABLE	Multipurpose wide angle application							--	MANDATORY	
4	Utility	--	ENUMERABLE	New borns/Neonatal							--	MANDATORY	
<b>PRODUCT TECHNICAL FEATURES</b>													
1	Compact design, light weight, easy to carry and use	--	ENUMERABLE	Yes							--	MANDATORY	
2	Digital Camera to photograph the interior surface of the eye including the Retina, Optic disc, Macula and posterior pole i.e Fundus	--	ENUMERABLE	Yes							--	MANDATORY	
3	Basic features inclusive		ENUMERABLE/ Multiselect	Mydriatic	Non-mydriatic	Color Imaging	Monochrome Imaging	FFA			--	GOLDEN PARAMETER	
4	Auto detection of eye position	--	ENUMERABLE	Yes							--	MANDATORY	
5	Stimulation filters	--	ENUMERABLE	Red	Blue						--	MANDATORY,FILTER	
6	Fixation target for wide angle fundus view	--	ENUMERABLE	External Fixation + 5 Internal Fixation Lamps	External Fixation + 9 Internal Fixation Lamps						--	GOLDEN PARAMETER	
7	External fixation lamps	--	ENUMERABLE	One							--	MANDATORY	
8	Internal fixation lamps	--	ENUMERABLE	Five	Nine						--	MANDATORY,FILTER	
9	Minimum pupil diameter (mm)	--	NUMERIC	3.0	3.3						--	MANDATORY,FILTER	
10	Illumination source	--	ENUMERABLE	Infrared LED							--	MANDATORY	
11	Field of view	--	ENUMERABLE	45 degree	50 degree	53 degree	At least 120 degrees from centre of the eye				--	GOLDEN PARAMETER	
12	Vertical tilting	--	ENUMERABLE	+/-12.5 degree							--	MANDATORY	
13	Horizontal tilting	--	ENUMERABLE	+/-30 degree							--	MANDATORY	
14	Working distance (mm)	--	NUMERIC	40							--	MANDATORY	
15	Camera type	--	ENUMERABLE	DSLR	HD SLR						--	GOLDEN PARAMETER	

16	Camera resolution (Mega Pixel)	--	NUMERIC	3							--	MANDATORY	
17	Focus way	--	ENUMERABLE	Auto focus	Manual focus						--	MANDATORY,FILTER	
18	Exposure way	--	ENUMERABLE	Auto flash	Manual flash						--	MANDATORY,FILTER	
19	Split-line aligning focusing	--	ENUMERABLE	Yes							--	MANDATORY	
20	FFA Imaging	--	ENUMERABLE	Yes	NA						--	MANDATORY,FILTER	
21	FFA video recording	--	ENUMERABLE	Yes	NA						--	MANDATORY,FILTER	
22	High image resolution for both vertical and horizontal	--	ENUMERABLE	Yes							--	MANDATORY	
23	Image resolution (Mega Pixel)	Must Declare, 16.2=<N=<24.1	NUMERIC	16.2 to 24.1							--	GOLDEN PARAMETER	
24	Video resolution (Fundus Fluorescein Angiography FFA) (Mega Pixel)	--	ENUMERABLE	0.42	NA						--	MANDATORY,FILTER	
25	True color for three RGB colors to diagnose any stage ROP (Retinopathy of Prematurity) in preterm	--	ENUMERABLE	Yes							--	MANDATORY	
26	Visulization of fundus for minimum pupil diameter even in non-dilated pupils	--	ENUMERABLE	Yes							--	MANDATORY	
27	Refractive Compensation range	--	ENUMERABLE	-15.0D ~ +15.0D	-25D~+30D						--	MANDATORY,FILTER	
28	Image storage and retrival for comparison over time for managing disease progression	--	ENUMERABLE	Yes							--	MANDATORY	
29	Small tip useful for even preterm babies	--	ENUMERABLE	Yes							--	MANDATORY	
30	Transmission of still images and video images for remote review with suitable net-working software to facilitate tele-medicine across networks and internet	--	ENUMERABLE	Yes							--	MANDATORY	
31	Instrument table	--	ENUMERABLE	With	Without						--	GOLDEN PARAMETER	
32	Seat movement (Back/Front, Left/Right, Up/Down)	--	ENUMERABLE	Yes							--	MANDATORY	
33	Report generation and printing	--	ENUMERABLE	Automatic	Manual						--	GOLDEN PARAMETER	
34	Size (LxWxD) (cmxcmxcm)	Must Declare	ENUMERABLE							cmxcmxcm	--	GOLDEN PARAMETER	
35	Weight (gm)	Must Declare	ENUMERABLE							gm	--	GOLDEN PARAMETER	
<b>USER'S INTERFACE</b>													
1	Data connection interface	--	ENUMERABLE	USB							--	MANDATORY	
2	Internet interface available	--	ENUMERABLE	Yes							--	MANDATORY	
3	Operating System	--	ENUMERABLE	Windows compatible version							--	MANDATORY	
4	Print facility of reports	--	ENUMERABLE	Yes							--	MANDATORY	
<b>ELECTRICAL FEATURES</b>													
1	Power supply	--	ENUMERABLE	220V+/-10%, 50/60 Hz Single Ph, AC							--	MANDATORY	
2	Input power (Watt)	0=<N=<300	ENUMERABLE	0 to 300							--	MANDATORY	

PACKING MODE												
1	Packing kit contains Product operating manual, warranty card, Retina/Fundus Camera, Accessories, Dehumidifier, Cleaning brush, Cleaning cloth and carrying box/hard case	--	ENUMERABLE	Yes							--	MANDATORY
2	Packing	--	ENUMERABLE	Individually packed							--	MANDATORY
ENVIRONMENTAL CONSIDERATIONS												
1	Capable of operating continuously in ambient conditions in ideal circumstances	--	ENUMERABLE	-5 deg C to +40 deg C, =<85% RH							--	MANDATORY
CERTIFICATIONS & REPORTS												
1	Submission of Test Report from Central Govt./NABL/ILAC accredited Lab to prove the conformity to declared specification at the time of supply	--	ENUMERABLE	YES							--	Mandatory
2	Product certification	--	ENUMERABLE	ISO 13485	EU-CE	US-FDA	EU-CE&US-FDA				--	MANDATORY,FILTER
3	Certification, performance and safety standards specific to the device	Must Declare like IEC 60601-1:2012, ISO 14971:2007, IEC 60601-2-18, IEC 6060-1-2	TEXT								--	MANDATORY
4	Submission of all the certifications and test reports to the buyer along with supplies on demand	--	ENUMERABLE	Yes							--	MANDATORY
INSTALLATION & TRAINING												
1	Supplier to perform installation, safety and operation checks before handover	--	ENUMERABLE	Yes							--	MANDATORY
2	Training of users in operation and basic maintenance shall be provided	--	ENUMERABLE	Yes							--	MANDATORY
WARRANTY & MAINTENANCE												
1	Warranty (Yrs)	--	NUMERIC	3	4	5					Years	GOLDEN PARAMETER
2	User technical and maintenance manual detailing complete maintaining schedule with routine maintenance should be provided	--	ENUMERABLE	Yes							--	MANDATORY
3	Contact details of manufacturer, supplier and local service agent to be provided	--	ENUMERABLE	Yes							--	MANDATORY

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