

File No.GEM/TP/ Double Lumen Endotracheal Tubes/2019 (Version 3.0)											DRAFT T/P			
LEVEL 1 CATEGORY: Medical Equipment and Accessories and Supplies - UNSPS Code 42000000														
LEVEL 2 CATEGORY: Respiratory and Anesthesia and Resuscitation Products - UNSPS Code 42270000														
LEVEL 3 CATEGORY : Airway Management Products - UNSPS Code 42271900														
Level 4 Category : Disposable Double Lumen Endotracheal Tubes - UNSPS Code 42271905											GEM Version 3.0			
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES							UNIT	CATEGORY OF FIELD	REMARKS	
<b>GENERAL FEATURES</b>														
1	Product Description	--	ENUMERABLE	Disposable Double Lumen Endotracheal Tubes (DLT)							--	MANDATORY		
2	Clinical Purpose	--	ENUMERABLE	To use in tracheal intubation during thoracic surgery and other medical conditions to achieve selective, one-sided ventilation of either the right or the left lung							--	MANDATORY		
3	Sterile and ready for use	--	ENUMERABLE	Yes							--	MANDATORY		
4	Method of sterilization	--	ENUMERABLE	Eto	Gamma						--	MANDATORY		
5	Disposable	--	ENUMERABLE	Yes							--	MANDATORY		
<b>PRODUCT INFORMATION</b>														
1	Type of Tube	--	ENUMERABLE	Right Sided Tube		Left Sided Tube						--	GOLDEN	
2	Material of Tube (Medical grade)	--	ENUMERABLE	100% Silicon		100% PVC		Silicon Coated PVC			--	GOLDEN		
3	Material of tube should be non toxic and latex Free	--	ENUMERABLE	Yes							--	MANDATORY		
4	DEHP Free Tube	--	ENUMERABLE	Yes							--	MANDATORY		
5	Cuffed tube ( Tracheal cuff and Bronchial cuff )	--	ENUMERABLE	Yes							--	MANDATORY		
6	The cuffs, two lumens and pilot balloons should be color coded for easy identification	--	ENUMERABLE	Yes							--	MANDATORY		
7	Kink resistant thermostatic tube	--	ENUMERABLE	Yes							--	MANDATORY		
8	Radio opaque line on tube	--	ENUMERABLE	Yes							--	MANDATORY		
9	Provision of Murphy eye	--	ENUMERABLE	Yes	No						--	GOLDEN		
10	Intubation depth marking on tube	--	ENUMERABLE	Yes							--	MANDATORY		
11	Size of the Tube (FR)	--	ENUMERABLE	26	28	32	35	37	39	41	FR	GOLDEN		
12	Provided with connector	--	ENUMERABLE	Yes	No						--	GOLDEN		
13	Size of Connector (mm)	--	ENUMERABLE	15 mm	22 mm	NA					--	MANDATORY, FILTER		
14	Provided with individual port blocking clamp	--	ENUMERABLE	Yes	No						--	GOLDEN		
<b>PACKAGING</b>														
1	Type of Packing for Tube	--	ENUMERABLE	Individually Packed in a Soft Wrap	Individually Packed in a Peelable Blister Pack	Individually Packed in a Poly Bag					--	GOLDEN		
<b>CERTIFICATIONS &amp; REPORTS</b>														
1	Availability of valid drug license issued from competent authority defined under Drugs and Cosmetics Act, 1940 (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	For Manufacture	For Sale						--	MANDATORY, FILTER	Multi Select	

2	Drug License Number	Must Declare	TEXT								--	MANDATORY	AKBNV
3	Drug License Date	Must Declare	TEXT								--	MANDATORY	AKBNV
4	Manufacturer certifications (Proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	ISO 13485	ISO 9001	GMP	WHO GMP				--	GOLDEN	Multi Select
5	Certification Number	Must Declare	TEXT								--	MANDATORY	AKBNV
6	Certification Date	Must Declare	TEXT								--	MANDATORY	AKBNV
7	Product Certifications (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	EU-CE	US-FDA						--	GOLDEN	Multi Select
8	Product Certification Number	Must Declare	TEXT								--	MANDATORY	AKBNV
9	Product Certification Date	Must Declare	TEXT								--	MANDATORY	AKBNV
10	Certificate issuing Authority	Must Declare	TEXT								--	MANDATORY	AKBNV
11	Availability of Test report from Central GOVT/NABL/ILAC accredited Lab or in house test report from parent manufacturer to prove the conformity to the declared specifications( proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	Yes							--	MANDATORY	
12	Availability of Biocompatibility testing certificate (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes							--	MANDATORY	
<b>SHELF LIFE</b>													
1	Shelf Life from the date of manufacture (in months)	--	NUMERIC	12	18	24	30	36			Months	GOLDEN	
2	The product should not have passed more than 1/6 of the total shelf life at the time of dispatch to the consignee	--	ENUMERABLE	Yes							--	MANDATORY	

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DY.CEO

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