

File No.GEM/TP/Haemostatic Gauze(Chitosan)/2018 (Version 3.0)							Draft T/P		
Level 1 Category: Medical Equipment and Accessories and Supplies -UNSPS Code 42000000									
Level 2 Category: Wound Care Products - UNSPS Code 42310000									
Level 3 Category: Wound Packing Products -UNSPS Code 42312400									
Level 4 Category: Haemostatic Gauze(Chitosan) - UNSPS Code 42311504							GEM Version 3.0		
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES			UNIT	CATEGORY OF FIELD	REMARKS
GENERAL FEATURES									
1	Product Description	--	ENUMERABLE	Haemostatic Gauze (Chitosan)			--	MANDATORY	
2	Clinical Purpose	--	ENUMERABLE	To control bleeding within minutes of application by acting as an active mechanical barrier to the wounded area			--	MANDATORY	
3	Non toxic medical grade non absorbable fibrous material of smooth texture	--	ENUMERABLE	Yes			--	MANDATORY	
4	Active Ingredient used for coating the gauge	--	ENUMERABLE	Chitosan or its derivatives			--	MANDATORY	
5	Hypoallergenic, Non exothermic and Non pyrogenic	--	ENUMERABLE	Yes			--	MANDATORY	
6	Flexible and active on both sides	--	ENUMERABLE	Yes			--	MANDATORY	
7	Sterile	--	ENUMERABLE	Yes			--	MANDATORY	
8	Method of sterilization	--	ENUMERABLE	ETO	Gamma			MANDATORY, FILTER	
9	For Single use only	--	ENUMERABLE	Yes			--	MANDATORY	
10	Can be cut, folded, stuffed into deep wounds	--	ENUMERABLE	Yes			--	MANDATORY	
11	Protects wound from infection	--	ENUMERABLE	Yes			--	MANDATORY	
12	Ready for instant use	--	ENUMERABLE	Yes			--	MANDATORY	
13	Easy to remove from wounds by irrigating with saline solution without causing any disturbance to the wound	--	ENUMERABLE	Yes			--	MANDATORY	
DIMENSIONS									
1	Size (L X W) in cm	--	ENUMERABLE	5cm x 5cm, 8cm x 5cm, 8cm x 8cm, 10cm x 10cm, 15cm x 15cm, 20cm x 20cm			cm x cm	GOLDEN	
2	Weight (gm)	Must Declare	MEASURABLE	20 to 30			gm	MANDATORY	
PACKAGING AND MARKING									
1	Type of packing	--	ENUMERABLE	Individually packed in a moisture proof peel open double layered pouch for easy carrying and withstand extreme temperature duly retaining the sterility and shelf life			--	MANDATORY	
2	Product shall be labelled with batch number, manufacturing license number, mfg date, expiry date, manufacturers address, storage condition, any specific direction for use etc	--	ENUMERABLE	Yes			--	MANDATORY	
3	Color indicator on the packing that product under pack is sterile	--	ENUMERABLE	Yes			--	MANDATORY	
CERTIFICATIONS & REPORTS									
1	DGQA Registered Supplier	--	BOOLEAN	Yes	No		--	MANDATORY, FILTER	
2	DGQA Registration Certificate Number if DGQA registered supplier	Must Declare	TEXT				--	MANDATORY	

3	DGQA Registration Certificate Date if DGQA registered supplier	Must Declare	TEXT				--	MANDATORY	
4	Valid Drug License available as	--	ENUMERABLE	Manufacturer	Seller		--	MANDATORY, FILTER	Multi Select
5	Drug License Number	Must Declare	TEXT				--	MANDATORY	
6	Drug License Date	Must Declare	TEXT				--	MANDATORY	
7	Product Certification	--	ENUMERABLE	ISO	EU-CE	US-FDA	--	MANDATORY, FILTER	Multi Select
8	Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification	--	ENUMERABLE	Yes			--	MANDATORY	
9	Submission of all the certifications, licenses and test reports at the time of supply to the buyer	--	ENUMERABLE	Yes			--	MANDATORY	
SHELF LIFE									
1	Shelf Life (in months)	--	NUMERIC	24	30	36	Months	GOLDEN	
2	The product should have shelf life of at least 2/3rd of the total shelf life at the time of supply	--	Yes				--	MANDATORY	

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