

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

Level 2 Category: Dental equipment and supplies -UNSPS Code 42150000

Level 3 Category: Dental operatory specific supplies -UNSPS Code 42152600

Level 4 Category: Collagen Membrane Barrier for Orthopedic & Dental Surgeries -UNSPS Code 42152602

DRAFT
T/P

GEM Version 3.0

S.No	PARAMETER	HINT	TYPE OF FIELD	VALUES	UNIT	CATEGORY OF FIELD	REMARKS
GENERAL FEATURES							
1	Type	--	ENUMERABLE	Resorbable collagen membrane (RCM)		MANDATORY	
2	Application	--	ENUMERABLE	Guided Tissue Regeneration or Guided Bone Regeneration		MANDATORY	
3	Usage	--	ENUMERABLE	Oral surgeons, Periodontists, Orthodontists, Endodontists and Orthopaedics		MANDATORY	
4	Utility	--	ENUMERABLE	Orthopaedic surgeries & Dental surgeries		MANDATORY	
PRODUCT INFORMATION							
1	Thin sheet	--	ENUMERABLE	Yes		MANDATORY	
2	Number of Sheets of membrane	--	ENUMERABLE	Single		MANDATORY	
3	Porus structure with smooth surface on other side	--	BOOLEAN	Yes	No	MANDATORY, FILTER	
4	Tissue side and Bone side indicated	--	BOOLEAN	Yes	No	MANDATORY, FILTER	
5	Bio-resorbable	--	ENUMERABLE	Yes		MANDATORY	
6	Highly bio-compatible	--	ENUMERABLE	Yes		MANDATORY	
7	Highly purified	--	ENUMERABLE	Yes		MANDATORY	
8	High mechanical strength	--	ENUMERABLE	Yes		MANDATORY	
9	Soft and drapable	--	ENUMERABLE	Yes		MANDATORY	
10	Does not stick to instruments	--	ENUMERABLE	Yes		MANDATORY	
11	Implantable for guided tissue regeneration of bone damages	--	ENUMERABLE	Yes		MANDATORY	
12	Easy to reposition for precise adjustment and placement as needed	--	ENUMERABLE	Yes		MANDATORY	
13	Sterile	--	ENUMERABLE	Yes		MANDATORY	
14	Method of sterilization	--	ENUMERABLE	EO	Gamma	MANDATORY, FILTER	

DIMENSIONS & MATERIAL														
1	Size (LxW) (mmxmm)	Must Declare	NUMERIC	10x10	15x20	20x30	30x40	15x30	25x30	17x25	20x25	mmxmm	GOLDEN PARAMETER	
2	Material of collagen membrane	--	ENUMERABLE	Manufactured from purified porcine/Bovine tissue	Derived from selected animal tissues and purified							--	GOLDEN PARAMETER	
STANDARD														
1	Product conformity to standard	--	ENUMERABLE	EU-CE	US-FDA	EU-CE&US-FDA						--	MANDATORY, FILTER	
PACKING & MARKING														
1	Packing type	--	ENUMERABLE	Sterile								--	MANDATORY	
2	Packing mode	--	ENUMERABLE	Sealed pack								--	MANDATORY	
3	Sealed pack printed with the details of Manufacturer name, description of drug, Lot No etc	--	ENUMERABLE	Yes								--	MANDATORY	
CERTIFICATIONS & REPORTS														
1	Submission of Test Report on form 39 or from Central Govt./NABL/ILAC accredited Lab to prove the conformity to declared specification at the time of supply	--	ENUMERABLE	Yes								--	MANDATORY	
2	Sould Confirm that the packing is original as manufactured by the OEM i.e not repacked or refurbished by the supplier	--	ENUMERABLE	Yes								--	MANDATORY	
3	Should produce copies of all documents for import, manufacture and sale as per Central Drugs Standard Control Organisation of India at the time of supply	--	ENUMERABLE	Yes								--	MANDATORY	
4	Tissue implantation testing certificate to be provided	--	ENUMERABLE	YES								--	MANDATORY	
5	Certifications Available	--	ENUMERABLE	ISO 13485	EU-CE	US-FDA	EU-CE & US-FDA					--	MANDATORY, FILTER	
6	Product conformity certificate is to be provided to the buyer at the time of supply	--	ENUMERABLE	Yes								--	MANDATORY	
7	Availability of valid manufacturing Drug License	--	ENUMERABLE	Yes								--	MANDATORY	
8	Drug License No	Must Declare	TEXT									--	MANDATORY	
9	Drug License Date	Must Declare	TEXT									--	MANDATORY	
SHELF LIFE														
1	Minimum shelf life at the time of supply (Yrs)	--	NUMERIC	2								Yrs	MANDATORY	
2	Replacement of sealed pack against manufacturing defects within shelf life	--	ENUMERABLE	Yes								--	MANDATORY	

(A. KESAVA RAO)
AD, GEM-SPV

(MANJU SHARMA)
DY. CEO

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