

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 operator specific supplies -UNSPS Code 42152600

Level 4 Category: Glass Ionomer Cement for Dentistry -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	Product	--	ENUMERABLE	Glass ionomer cement (GIC) or Glass Poly alkeonate cement, conventional										--	MANDATORY
2	Purpose	--	ENUMERABLE	Luting	Restorative	Liner/Base	Pit & Fissure sealant	Orthodontic luting purposes	Core build-up material	High Fluoride releasing command set	Atraumatic Restorative Treatment (ART)	Pediatric Glass Ionomer Cements		--	MANDATORY, FILTER
3	Usage	--	ENUMERABLE	GIC is dental restorative material used for cavity lining, cavity restorations, long term luting of fixed prostheses, sealing pits and fissures, fixing orthodontic brackets, tooth erosion, tooth abrasion, dental restoration, restoration of deciduous teeth, tunnel restorations etc.									--	MANDATORY	
PRODUCT INFORMATION															
1	Supplied in powder and liquid components	--	ENUMERABLE	Yes										--	MANDATORY
2	Increased release of fluoride from GIC prevents enamel decalcification	--	ENUMERABLE	Yes										--	MANDATORY
3	Low solubility	--	ENUMERABLE	Yes										--	MANDATORY
4	Simple in the preparation of mixture (Powder, water mixture on a paper pad mixed with a specula to form a paste before apply in the defect area)	--	ENUMERABLE	Yes										--	MANDATORY
5	Coating agent or unfilled bonding resin is applied to protect excess cement at the margins of use to dry	--	ENUMERABLE	Yes										--	MANDATORY
6	Setting time for reaction of acid based to form hard reasonably strong material with acceptable appearance	--	ENUMERABLE	1.5 to 8 minutes	1.5 to 6 minutes									--	MANDATORY
MATERIAL COMPOSITION															
1	Powder composition	--	ENUMERABLE	Silica, Alumina, Aluminium fluoride, Calcium fluoride, Sodium fluoride, Aluminium phosphate, Strontium, Barium or Zinc Oxide									--	MANDATORY	
2	Liquid composition	--	ENUMERABLE	Polyacrylic acid	Itaconic acid	Malic acid	Tartaric acid	Water						--	MANDATORY, FILTER
STANDARD															
1	Product conformaty to standard	--	ENUMERABLE	EU-CE	US-FDA	EU-CE&US-FDA	IS/ISO 9917(Part 1- 2007)							--	MANDATORY, FILTER
PACKING & MARKING															
1	Kit contents	--	ENUMERABLE	55gm Powder, 50ml Liquid, Mixing pad, spoon	15gm powder, 15ml liquid, Mixing Pad, spoon	15g powder, 10ml liquid, Mixing pad, spoon								--	GOLDEN PARAMETER
2	Packing mode	--	ENUMERABLE	Small Carton box										--	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	Certifications Available	--	ENUMERABLE	IS/ISO 9917(Part 1- 2007	EU-CE	US-FDA	EU-CE & US-FDA						--	MANDATORY, FILTER
3	Product conformity certificate is to be provided to the buyer at the time of supply	--	ENUMERABLE	Yes									--	MANDATORY
4	Availability of valid manufacturing Drug License	--	ENUMERABLE	Yes									--	MANDATORY
5	Drug License No	Must Declare	TEXT										--	MANDATORY
6	Drug License Date	Must Declare	TEXT										--	MANDATORY
SHELF LIFE														
1	Minimum shelf life at the time of supply (Yrs)	--	NUMERIC	2									Yrs	MANDATORY

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