

File No.GEM/TP/Sterilization indicator tapes/2018 (Version 3.0)										DRAFT T/P FOR VERSION 3.0		
Level 1 Category: Medical Equipment and Accessories and Supplies -UNSPS Code 42000000												
Level 2 Category: Medical cleaning and sterilization products -UNSPS Code 42280000												
Level 3 Category: Sterilization indicators and controls -UNSPS Code 42281800												
Level 4 Category: Sterilization indicator tapes for Medical Purposes -UNSPS Code 42281807										GEM Version 3.0		
S.No	PARAMETER	HINT	TYPE OF FIELD	VALUES					UNIT	CATEGORY OF FIELD	REMARKS	
GENERAL FEATURES												
1	Product	--	ENUMERABLE	Sterilization/autoclave indicator tape for Medical purposes						--	MANDATORY	
2	Type	--	ENUMERABLE	Single sided, self adhesive						--	MANDATORY	
3	Usage	--	ENUMERABLE	Sterilization indicator tape is used in sealing or packaging to distinguish between sterilized and non-sterilized units during storage.						--	MANDATORY	
4	Utility	--	ENUMERABLE	This sterilization indicator tape is used to secure the packs wrapped with woven, non-woven, treated woven, paper and paper/plastic wraps that go into sterilizer and verify the packs that have been exposed to Hydrogen Peroxide. Indicator color does not fade when exposed to light.						--	MANDATORY	
5	Easily removable, residue free	--	ENUMERABLE	Yes						--	MANDATORY	
6	Highly resistant to break or tear	--	ENUMERABLE	Yes						--	MANDATORY	
7	Good resistant to heat and moisture	--	ENUMERABLE	Yes						--	MANDATORY	
8	Tape shall be Lead free and Non - toxic	--	ENUMERABLE	Yes						--	MANDATORY	
9	Strong tape, will firmly holds to package before, during and after sterilization cycle	--	ENUMERABLE	Yes						--	MANDATORY	
10	Tape shall stick well on paper, board, metal, plastic, glass etc	--	ENUMERABLE	Yes						--	MANDATORY	
PRODUCT TECHNICAL REQUIREMENTS												
1	Method of sterilization	--	ENUMERABLE	EO	ETO	Gamma	Gas Plasma	Steam		--	MANDATORY, FILTER	
2	Colour of tape before steriliation	--	ENUMERABLE	White	Cream	Green	Beige			--	MANDATORY, FILTER	
3	Colour of tape after steriliation/autoclave	--	ENUMERABLE	Brown	Black	Yellow				--	MANDATORY, FILTER	
4	Change of the integrated chemical indicator on the tape changes	--	ENUMERABLE	Its colour	Its display diagonal stripes	The word as "sterile"	The word as "autoclaved"				MANDATORY, FILTER	
5	After the sterilization process is complete, the tape can easily be removed with no adhesive residue.	--	ENUMERABLE	Yes						--	MANDATORY	
6	Tape provides an indication that the pack has passed through a sterilization cycle.	--	ENUMERABLE	Yes						--	MANDATORY	
7	Storage temperature range (Deg C)	Must Declare	TEXT							Deg.C	MANDATORY	
8	Storage humidity range (%RH)	Must Declare	TEXT							(%)	MANDATORY	
9	Sterilization temperature (Deg C)	Must Declare	TEXT							Deg.C	MANDATORY	
10	Sterilization relative humidity (RH) (%)	Must Declare	TEXT							(%)	MANDATORY	
11	Sterilization time (Minutes)	Must Declare	TEXT							Minutes	MANDATORY	
12	Exposition	Must Declare	TEXT							--	MANDATORY	

13	Shelf life of tape (year)	--	ENUMERABLE	1	2	3		Years	GOLDEN PARAMETER
----	---------------------------	----	------------	---	---	---	--	-------	------------------

DIMENSIONS, MATERIAL & WEIGHT										
1	Tape Length (meters)	--	ENUMERABLE	50	55	90			meter	GOLDEN PARAMETER
2	Tape width (mm)	--	ENUMERABLE	18	19	50			mm	GOLDEN PARAMETER
3	Core diameter of roll (mm)	Must Declare	TEXT						mm	MANDATORY
4	Material of tape backing	--	ENUMERABLE	Crepe Paper	Semi-creaped paper	Non-cellulose plastic backing with pressure sensitive adhesive			--	MANDATORY, FILTER
5	Other side of tape	--	ENUMERABLE	Chemical indicator Stripes that change in colour on sterilization					--	MANDATORY
6	Weight (gm)	--	NUMERIC	60	70	80	90	100	gms	GOLDEN PARAMETER
STANDARD										
1	Conformity to Standard	--	ENUMERABLE	ISO 18472:2006 Sterilisation of Health care products- Biological and Chemical indicators					--	MANDATORY
2	ISI Marked	--	BOOLEAN	Yes	No				--	MANDATORY
3	CM/L No.(if product is ISI marked)	Must Declare (Write '0' if not applicable)	TEXT						--	MANDATORY
PACKING										
1	Packing	--	ENUMERABLE	Individually packed in peel-to-open paper/polyethene pouch					--	MANDATORY
CERTIFICATION & REPORTS										
1	Submission of test report on Form 39 or from Central Govt. /NABL / ILAC accredited Lab covering all the parameters declared	--	ENUMERABLE	Yes					--	MANDATORY
2	Certification available	--	ISO	EU-CE	US-FDA	EU-CE & US-FDA			--	MANDATORY
3	Product conformity certificate is to be provided to the buyer at the time of supply	--	Yes						--	MANDATORY

(MANJU SHARMA)
DY.CEO

(A. KESAVA RAO)
AD, GEM-SPV