

File No.GEM/TP/First Field Dressing/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: BANDAGES AND DRESSINGS AND RELATED PRODUCTS - UNSPSC CODE --42311500										
Level 4 Category: First Field Dressing for Soldiers -- UNSPSC CODE- 42311523										GEM Version 3.0
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES				UNIT	CATEGORY OF FIELD	REMARKS
GENERAL										
1	Product Description	--	ENUMERABLE	First Field Dressing Bandage intended to be carried by soldiers for immediate use in case of (typical gunshot) wounds				--	MANDATORY	
2	Conformity to standard	--	ENUMERABLE	First Field Dressing as per DGQA Specification No. Prov/S/4665/TC-1(a)/2016/01				--	MANDATORY	
PRODUCT COMPONENTS AND DIMENSIONS										
1	Complete size of FFD (mmxmm)	--	ENUMERABLE	150x1500					mmxmm	MANDATORY
2	Brown Crepe bandage size (mmxmm)	--	ENUMERABLE	150x1200					mmxmm	MANDATORY
3	White Warp knitted bandage size (mmxmm)	--	ENUMERABLE	150x300					mmxmm	MANDATORY
4	FFD is with acrylic pressure sensitive adhesive strip	--	ENUMERABLE	Yes					--	MANDATORY
5	Size of acrylic pressure sensitive adhesive strip (mmxmm)	--	ENUMERABLE	40x130					mmxmm	MANDATORY
6	FFD is with high absorbent non-woven batting pad	--	ENUMERABLE	Yes					--	MANDATORY
7	Size of high absorbent non-woven batting pad (mmxmm)	--	ENUMERABLE	130x180					mmxmm	MANDATORY
8	Anti-microbial treated	--	ENUMERABLE	Yes					--	MANDATORY
9	Wound side PE mesh	--	ENUMERABLE	Yes					--	MANDATORY
10	PE mesh shall be impregnated/coated with non-leachable silver as antimicrobial treatment. .	--	ENUMERABLE	Yes					--	MANDATORY
11	Wound pad size (mmxmm)	--	ENUMERABLE	150x200					mmxmm	MANDATORY
12	Plastic ridge size (mmxmmxmm)	--	ENUMERABLE	125x50x12					mmxmmxmm	MANDATORY
13	Should have Plastic floating buckle made of Acrylonitrile butadiene styrene(ABS) or HIPS, so as to adjust fitting of dressing on affected part of the body.	--	ENUMERABLE	Yes					--	MANDATORY
14	Should have spun bond non-woven brown cloth	--	ENUMERABLE	Yes					--	MANDATORY
15	Non-woven brown cloth size	--	ENUMERABLE	140x140					mmxmm	MANDATORY
16	It should have micro hook Velcro tape 3B of size 50x140mm	--	ENUMERABLE	Yes					--	MANDATORY
17	It should have micro hook Velcro tape 3C of size 25x150mm	--	ENUMERABLE	Yes					--	MANDATORY

FUNCTIONAL REQUIREMENTS

1	The dressing should be able to act as primary hemostat device for management of moderate-to-serious injuries allowing air to circulate over the skin while covering the wound.	--	ENUMERABLE	Yes					--	MANDATORY
2	Material of First Field Dressing bandage	--	ENUMERABLE	Cotton					--	MANDATORY
3	Latex-free and non-allergic for prolonged use in field conditions	--	ENUMERABLE	Yes					--	MANDATORY
4	The compression should be increased in increments with every wrap turn around the limb	--	ENUMERABLE	Yes					--	MANDATORY
5	The dressing should be capable of providing antiseptic environment in which the wound can be covered fully	--	ENUMERABLE	Yes					--	MANDATORY
6	The dressing should have the capability of absorption of blood and other body fluids.	--	ENUMERABLE	Yes					--	MANDATORY
7	Sterilized	--	ENUMERABLE	Yes					--	MANDATORY
8	Method of sterilization	--	ENUMERABLE	ETO	Gamma				--	MANDATORY
9	The dressing shall comply with the requirements of the sterility when tested as per IS: 10150-1981 (RA 2000).	--	ENUMERABLE	Yes					--	MANDATORY
10	The dressing shall withstands the Water Immersion Test given in DGQA Specification No. Prov/S/4665/TC-1(a)/2016/01	--	ENUMERABLE	Yes					--	MANDATORY
11	Disposable	--	ENUMERABLE	Yes					--	MANDATORY

LABELING AND MARKING

1	Product Label printed with Nomenclature, DS Cat number and PVMS number of the store, Name or Trade mark of the Manufacturer, Manufacturing batch number, Month and year of manufacture, Sterility mode, Direction to use etc	--	ENUMERABLE	Yes					--	MANDATORY
2	Dimension of Product label (mm x mm)	--	ENUMERABLE	80 x 60					--	MANDATORY
3	The printed product label shall be placed between the inner and outer polyethylene bags	--	ENUMERABLE	Yes					--	MANDATORY

PACKING & MARKING

1	The FFD should be encased in two layers of packing, the inside pouch made of medical grade packing paper at back and polyester laminate polyethylene transparent sheet on top. The second and outer pack of complete polyester laminated Polyethylene sheet of 75 micron thickness, which allows the dressing to retain its sterility and also be provided with tear notches to allow easy opening of the plastic cover.	--	ENUMERABLE	Yes					--	MANDATORY
2	The Packing shall be water proof	--	ENUMERABLE	Yes					--	MANDATORY

3	The FFD should be vacuum packed to protect sterility.	--	ENUMERABLE	Yes					--	MANDATORY	
4	Color indicator to show wheather the sterility inside the pack is being maintained or not	--	ENUMERABLE	Yes					--	MANDATORY	
5	Necessary instructions for field use and method application written in bilingual, i.e Hindi & English text along with diagrammatic representation shall be provided between inner and outer pack cover with each FFD in the form of leaflet of suitable size thus allowing the soldier in combat environment to easily use it.	--	ENUMERABLE	Yes					--	MANDATORY	
6	The outer boxes shall legibly and indelibly be marked with DS Cat No, PVMS No and nomenclature of the store, Quantity packed preceded by abbreviation 'Qty', Name and address of the consignee, Mass of the package in kg, Package No./Carton No, Month and year of packing, Redcross mark on a white circular background at two sides of the package, Defence acceptance mark of suitable size at right top Corner, Month and year of manufacture and date of expiry	--	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	Certification for Manufacturing Premises	--	ENUMERABLE	ISO	EU-CE	US-FDA	EU-CE&US-FDA	GMP	--	MANDATORY, FILTER	
3	A certificate/Undertaking in respect of free from chlorine shall be submitted by OEM (Original equipment manufacturer) for wound pad	--	ENUMERABLE	Yes					--	MANDATORY	
4	A certificate/Undertaking in respect of adhesive strip for hypo allergenic, non toxic& non-irritating shall be submitted by OEM.	--	ENUMERABLE	Yes					--	MANDATORY	
5	Product conformity certificate is to be provided to the buyer at the time of supply	--	ENUMERABLE	Yes					--	MANDATORY	
6	Availability of Valid Drug License	--	ENUMERABLE	Yes					--	MANDATORY	
7	Drug License No	Must Declare	ENUMERABLE						--	MANDATORY	
8	Drug License Date	Must Declare	ENUMERABLE						--	MANDATORY	
9	Minimum Shelf life (Yrs)	--	NUMERIC	5					Yrs	MANDATORY	
10	Warranty (months)	--	NUMERIC	12	15				month	MANDATORY	

(A. KESAVA RAO)
AD, GEM-SPV

(MANJU SHARMA)
DY.CEO

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