FILE No.													
Creator Ritika Gupta Moderator : Shri A.V.Muralidharan (Dy. CEO GeM) Approver : A.K Kamra													
	Sub Category : Silk Protein Based Non Adherant Sterile Dressing												
S.No.	Parameters			Value 1	Value2	Value 3	Value 4	Value 5	Validation	Golden parameter	Priority	Unit	Demand Aggregation
1	Purpose			Bilaminated surgical wound cover for Partial thickness burn wounds,Skin graft donor sites,Chronic skin ulcers and other non infected wounds	Bilaminated surgical wound cover for Partial thickness burn wounds,Skin graft donor sites,Chronic skin ulcers and other non infected wounds as well as infected wounds					G			
2	Base material of wound cover	P	E	Silk protein derived bio modified sheet(Non mammalian source)									
3	Composition / Ingredients	P	E	Silk Protein / Activated Silk Matrix with Centella Asiatica Herbal Extract	Silk Protein / Activated Silk Matrix	Silk Protein / Activated Silk Matrix with Centella Asiatica Herbal Extract along with silver oxide	Silk Protein / Activated Silk Matrix along with silver oxide						
4	Type of wound cover			sheet	mesh	Sheet with PU Foam Support							
5	Bilaminate Feature of sheet/mesh	P	E	One surface Hydrphobic and other Hydrophilic									
6	Hydrophilic side			Comes in to contact with the wound and absorbs the exudates									
7	Hydrophobic side			Do not allow atmospheric moisture to get in but allows free passage of air through micro pores of the film									
8	Sterilization	P	N	with Gamma radiation									
9	Sizes in cm x cm	P	N	5x5	10x10	10x25	20x25	20x40					
10	Absorbability	P	E	Highly absorbent									
11	Maintains an optimal moist enviornment for faster wound healing	P	E	yes									

12	Forms protective breathable barrier	P	E	yes									
13	Moisurizes and protects peri wound skin	P	E	yes									
14	Dermis proliferation leading to high cell attatchment and tissue regeneration	P	E	yes									
15	creates and maintains an enviornment that is favorable for healing and re epithelialisation	P	E	yes									
16	Reduces Scar formation and has superior pain index within 24 hours of application	P	E	yes									
17	Type of use	P	E	single use and disposable									
18	Number of days of usage	P	E	7									
19	pack size	P	E	5	10	25							
20	Drug licence no and date	P	T										
21	ISO Certification for manufacturer	P	E	ISO 9001:2015									
22	ISO Certification no and date	P	T										
23	ISO certification for quality standards	P	E	ISO 13485:2016									
24	ISO Certification no and date	P	T										
25	Copies of certification and reports to be submitted to buyer on demand	P	E	yes									