


PRODUCT SPECIFICATION


PART I. PRODUCT IDENTIFICATION	
Brand	INNOMED
Code No.	S74068
Product Name	SILICONE FOAM DRESSING
Size	20cmX50cm
Color	WHITE COLOR /SKIN COLOR
Material	Film property - absorbent dressing based on silicone and hydrophilic polyurethane for carrying exudate, sterile, disposable.
	Absorbent body of viscose fibers; polyethylene anti-adhesive mesh.
	3-layer foil component: - polyurethane foam layer; - soft silicone layer; - polyethylene film. With capacity to transfer the exudate in the secondary dressing.
	Silicone paper support and application system composed of two pieces of polyester film.
Technical Characteristics	1.Sterile, 1pc/package
	2.The minimum duration of placement on the wound without being changed 3 -7 days
	3.Silicone-based adhesive with atraumatic technology, with the ability to prevent maceration
	4.Possibility of use with topical preparations. No allergenic properties, hypoallergenic.
	5.Adaptability: 1.2N / cm.
	6.Absorption capacity of the absorbent body:> 11g / 100cm ² .
Applications	Ideal for post-operative use, also used in accident & emergency for cuts, laceration and sutured wounds. Applicable for cases of Epidermolysis bullosa.
Type of Product	Medical disposable
Sterilization Method	EO (ethylene oxide)
Storage Instruction	Store in dry, ventilative condition, with ordinary temperature.
Picture	

PART II. QUALITY SYSTEM & STANDARD	
Classification	IIb, rule 4
Standard	CE (EU-MDR)

Quality Management Systems & No.	ISO13485
	Q5 083478 0025 Rev. 02
Production Quality Assurance System & No.	CE
	G10 083478 0030 Rev.00, exp. 2028-04-10
CE Conformity Assessment Route	Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
Certification Body	TUV SUD Product Service GmbH

PART III. PACKAGING INFORMATION							
Size	Individual Packaging		Secondary Packaging		Outer Packaging		
	Qty	Material	Qty	Material	Qty	Dimensions	Material
20cmx50cm	1	sterile pouch	1	Box	100	46.5*22*24cm	carton

Zhejiang Longterm Medical Technology Co., Ltd
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 Mr. Bo Xu, Management representative
2024.06.13