

Product Specification – Axiostat 8x8cm Haemostat Patch

Product Information

Description:	Axiostat 8x8cm Haemostat Patch		
REF:	10030		
Manufacturer REF:	L88		
Manufacturer:	Axio Biosolutions Private Limited		
Address:	Plot No 18, Gujarat Pharma Techno Park, Sari Matoda, Sanand Taluka,		
	Ahmedabad - 382220, Gujarat, India		
EC Rep:	Emergo Europe B.V.		
Address:	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands		
Intended Use:	To control moderate to severe bleeding. Suitable for combat injuries.		
Characteristics:	- 100% chitosan haemostatic dressing.		
	- Provides mechanical barrier against bleeding site.		
	- Can be cut, folded or stuffed into deep wounds.		
	- Easy to apply and remove.		
	 Works on a charge based mechanism of mucoadhesion which forms a 		
	mechanical barrier to the bleeding site.		
Sterile:	Yes – Gamma sterilized		
Storage Conditions:	Room temperature		



The information contained in this product specification is accurate for the above revision date. However, components are subject to change without notice, when another specification will be issued.



Barcode Information

UNIT	QUANTITY	BARCODE	DIMENSIONS	WEIGHT
Single	Single	8908004039106	140mm x 110mm x 13mm	15g
Box	Box of 10	-	150mm x 130mm x 107mm	155g
Case	Case of 360	-	580mm x 360mm x 470mm	7.75kg

Additional Information

Moisture Content:	Not more than 35% of its weight		
Absorbency:	Not less than 15 times of its weight		
pH:	5.0 - 7.0		
Dispersion:	Product remains intact		
Tensile Strength:	Not less than 5N/25mm		
Seal Strength:	Not less than 1.5N/15mm		
Bacterial Endotoxin:	<20 EU/Device		
Biocompatibility Profile:	Cytotoxicity - Non-cytotoxic		
	Skin Sensitization Study - No evidence of delayed dermal contact sensitization		
	Intracutaneous reactivity Study - No evidence of significant irritation		
	Acute Systemic Toxicity - No mortality or systemic toxicity		
	Pyrogen test - Non-pyrogenic		
	Haemolysis - Non-Haemolytic		
	Bacterial Endotoxin Test - Endotoxin units per device in Axiostat is less than 20 EU		