

# CHITOSAM® | TECHNICAL DATA SHEET

## PRODUCT DESCRIPTION

The ChitoSAM® 100 Product Family is a high-performance hemostatic dressing designed to stop moderate to severe bleeding fast. The non-woven dressing is spun directly from chitosan which is derived from crustaceans or snow crab shells. The dressings contain no cotton, rayon or polyester. ChitoSAM® is easy to use, extremely effective, and works independently of the body's normal clotting processes.

## PRODUCT SPECIFICATIONS

### MATERIALS AND SPECS

- Description: 100% chitosan hemostatic dressing
- Size: Available in four sizes - 4" X 4" Single Ply, 3" x 4' Z Fold and 3" x 6' Z Fold
- Sterilization Method: Gamma irradiation
- Shelf Life: 5 years

### INDICATIONS FOR USE

- The Chito-SAM® 100 products are for the control of moderate to severe bleeding and management of external abrasions, lacerations, puncture wounds.

### INSTRUCTIONS FOR USE

- 1) Use appropriate size and number of dressings based on wound area and amount of bleeding.
- 2) Apply dressing directly to the wound.
- 3) To control bleeding, apply firm pressure for 3 minutes. Secure with adequate cover dressing, maintaining pressure to the wound.
- 4) Use sterile saline or water to rinse any dressing remnants from the wound when removing.

### PACKAGING

- Pouch design allows for quick access and is tearable from any side.
- Product is packaged individually in a sealed foil package.
- Multiple units may be packaged for shipment in a corrugated cardboard box.

## DEVICE MODELS

PRODUCT DESCRIPTION	PART NUMBER   CE-MARKED	PART NUMBER   NON-CE	NSN
ChitoSAM 100 4" X 4" Single Ply	CT101-A-EN	CT100-A-EN	
ChitoSAM 100 3" x 4' Z Fold	CT101-B-EN	CT100-B-EN	
ChitoSAM 100 3" x 6' Z Fold	CT101-C-EN	CT100-C-EN	6510-01-682-6901

## COMPLIANCE

- CE Marked (Only part numbers: CT101-A-EN, CT101-B-EN, and CT101-C-EN)
- ISO 13485: 2016 Certificate
- MDD Certificate Registration: 252.820 (issued by NSAI)
- Authorized Representative: Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, NL