

Product name	SpeedM® Emergency Hemostatic Dressing						
Reference number	CG01E						
Product category	Hemostatic agent						
Product group	Non-absorbable						
Notified Body Number	DNV Medcert GmbH; Pilatuspool 2, 20335 Hamburg, Germany						
EC certificate number	0482 20359GB448241002						
Product image	1 piece Dispenser box with 15 pieces Shipping carton with 180 pieces   						
Description	SpeedM® emergency hemostatic dressing is a sterile, 7.5 x 370 cm, radiopaque, Z-fold hemostatic dressing and is packaged for aseptic removal. This product contains Halloysite.						
Intended purpose	SpeedM® is an emergency hemostatic dressing intended for temporary treatment of heavily bleeding traumatic injuries. The product is suitable for any patient to whom the intended purpose can be applied. The product is not suitable for children under 6 years of age.						
Dimension	7.5 x 370 cm, Z-fold						
Packaging unit	1 Dispenser box with 15 pieces, individually sterile packed						
Packaging Dimension	Unit		Dimension		Weight		
	piece		ca. 10,5 x 14,0 x 2,2 cm		23g		
	Dispenser box		15,5 x 38,7 x 9,3 cm		618 g gross; 494 g net		
	Shipping Carton		40,0 x 58,5 x 33,5 cm		8,3 kg gross; 5,9 kg net		
Stock requirement	18 - 25°C						
Shelf life	5 years						
Transport stability	-30 – 60°C						
Preparation time	Ready for use						
Material	perforated nonwoven fabric coated with ultrafine halloysites						
UDI/GTIN	GTIN/UDI	Produktebene	Brand	Language	Quantity	Unit of Measure	
	4262377860021	Piece	SpeedM	Englisch	1	pieces	
	4262377860014	Dispenser Box	SpeedM	Englisch	15	pieces	
	4262377860052	Shipping Carton	SpeedM	Englisch	180	pieces	
GMDN code	47917 Inorganic haemostatic agent, sterile						
EMDN	M040599 Emergency Hemostatic Dressing						
DUNS	314388771						
Nomenclature code	10-965						
Nomenclature term	Dressing						
Category	Products for single use						
Customs number/ HS code	3005 9031						
Indication	SpeedM® emergency hemostatic dressing is intended for temporary treatment of heavily bleeding wounds such as cuts, lacerations and abrasions. The product can also be used for temporary treatment of traumatic injuries and heavily bleeding wounds. For use by trained first responders.						
Contra indication	SpeedM® is not indicated for use on the eyeball as there may be a risk of dehydration or pressure damage. The product is not indicated for use in or in direct contact with the central circulatory system. SpeedM® must not be used in patients with a known allergic reaction to kaolins.						
Mode of action	The mechanism of action of SpeedM® is based on purely physical phenomena: the local concentration of platelets through electrostatic adhesion, water absorption and pressure transfer. In addition, the very large specific surface area of the overall product (HNT mineral + gauze) has a favorable effect.						