

		Technical Data Sheet	
Hydrosorb® Gel			Spec.-No.: D 4.0010
			Department: CMO-DMW
			Date: 2016-12-13

1. General Product Description

Hydrosorb® Gel is a clear and viscous gel based on Ringer's solution and glycerine.

Hydrosorb® Gel carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class II b medical device.

A conformity assessment has been performed for Hydrosorb® Gel and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use and effectiveness of Hydrosorb® Gel, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

For moist wound treatment of superficial and deep wounds with a low exudation (e.g. leg ulcers, pressure sores and burn wounds grade 2b; supports an autolytic débridement; the wound has to be covered with a 5 mm thick layer of the gel and an appropriate secondary dressing.

3. Presentations

Sterile gel in syringes of 8 g or 15 g




4. Product Characteristics

Composition of Hydrosorb® Gel

Gel forming agents	Hydroxyethylcellulose, Carboxymethylcellulose, Carbomer
Water component	Ringer's solution
Moisturizer	Glycerine

5. Product Requirements

Gel	clear and viscous gel
Ejectable amount	min. 8 g
	15 g (± 0.5 g)
refraction index (20°C)	1.355-1.365
pH- value	5.00 – 7.50

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6. Labelling

Lot-No. with 9-digit code:

e.g.:

X	XXX	88	XXX
year	for internal purposes only	Manufacturer	for internal purposes only

Expiry date:

e.g.:  03.2013
MM.YYYY

Shelf life: 3 years

7. Packaging

10 syringes (single syringe sealed in a PE-pouch) in a folding box of 15 g product, 5 syringes (single syringe sealed in a PE-pouch) in a folding box of 8 g product.

10 folding boxes per transport box acc. DIN, sealed with adhesive tapes, packed onto Euro pallet.

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