


- Device classification: Class I
- Complies with the 93/42/CEE directive


 DIAGRAMM HALBACH GmbH & Co. KG, D-58239 SCHWERTE, GERMANY

<i>General description</i>	Salt-free, oil-free, paraben-free, water- and lipid-soluble, non-irritating and non-oxidizing sonography, ECG, Doppler and ultrasound transmission gel, and without damage to the electrodes. Clinical brand.	
<i>Attachments</i>	Yes	Photo
<i>Batch reference</i>	Yes	See on the container.
<i>Connected device</i>	Yes	Ultrasound or sonography probe.
<i>Single use device</i>	Yes	Do not re-use the gel on the skin, cross contamination risk.
<i>Sterile device</i>	No	
<i>Sterilisation</i>	No	
<i>Autoclavable</i>	No	
<i>Cleaning</i>	No	
<i>Unsuitable substance</i>	Do not mix with any product.	
<i>Component parts</i>	No	
<i>Material</i>	Carbomer (0.3-1%), triethanolamine (0.3-1%), monopropylene glycol (0.5-2%), methychloroisothiazoline and methylisothiazolin (0.05-0.15%), deionized water (qsp 100%)	
<i>Labelling</i>	Yes	(See marking on medical device)
<i>Packaging</i>	Yes	5l cubitainer or 250ml bottle
<i>Special packaging</i>	Yes	In a clean, dry place, away from heat sources. Avoid frost. Avoid temperature fluctuations.
<i>Marking on medical device</i>	Yes	Designation on the bottle or cubitainer, ingredients, quantity, batch, expiry date.
<i>References + extensions</i>	67 310 05	67 310 25
<i>Designation</i>	Pump-free 5l cubitainer	250ml bottle
<i>Dimensions L x W x H (mm)+- 3mm</i>	Approximately: 170 x 190	Ø = 50 H = 175
<i>Content / Capacity (ml)</i>	5000	250
<i>Net weight (g)+1%</i>	5403	283
<i>Colours</i>	Blue/Transparent	
<i>pH (20°C)</i>	6 - 8	
<i>Water soluble as %</i>	100	
<i>Flammability</i>	Non-flammable	
<i>Toxicity</i>	Non-toxic	
<i>Allergy</i>	Non-allergic, avoid contact with eyes.	
<i>Usage</i>	Medical device for adequate wave transmission for sonography-probe and ultrasound-electrode examinations. Can be used with defibrillator electrodes.	
<i>Instruction for use</i>	Not necessary for class I and IIa devices, if they can be used safely without the help of such instructions. See essential requirements of Directive 93/42/EEC (Annex I Section 13.1)	
<i>Precautions for use</i>	Close container properly after each use and store adequately. Avoid contact with eyes and mucous membranes. For external use only.	
<i>Recycling</i>	No	
<i>Recovery</i>	For the container in the waste bin.	
<i>WEEE/REACH</i>	No/NA	
<i>Phthalates</i>	No	
<i>Safety data</i>	R-Phrases = None    Combination phrases = None	