

Technical Data Sheet

Rev. 2020.05

REF	Description
9791288	Ultrasound gel 250g
9791289	Ultrasound gel 1000g
9791290	Ultrasound gel 5000g cubitainer
9791291	Ultrasound gel 5000g canister
9791292	Ultrasound gel 10000g cubitainer
9791324	Ultrasound gel 10000g canister

- Distributor:** CB Healthcare Consulting GmbH
Am Neumarkt 34 - 22041 Hamburg – Germany
- Intended Use:** Contact Agent for ultrasound therapy and diagnostics
- Application:** The gel is applied locally and wiped off immediately after the examination.
- Patient contact:** non-invasive (RL 93/42 / EWG)
Surface contact with uninjured skin (EN ISO 10993-1)
- Contact time:** temporary: less than 60 minutes (RL 93/42 / EEC)
short-term: up to 24 hours (EN ISO 10993-1)
- Classification:** Class I / Rule 5 according to Annex IX of Directive 93/42 / EEC
- Composition/Components:** Distilled water
Cabomer
Glycerin 85%
Sodium hydroxides
Propylene glycol
Benzyl Alcohol
Methylchloroisothiazolinone
Methylisothiazolinone

Specifications:

Characteristic	Method	Setpoint
Appearance	Visual	clear, viscous gel; no air bubbles
odor	Olfactory	odorless
pH-Value	Ph. Eur. 2.2.3	5.8 – 6.4 (at 20°C / 68°F)
Viscosity	PH. Eur. 2.2.10	900.000 – 3.000.000.mPa*s (at 20°C / 68°F)

Microbiological Quality:

	Method	Setpoint
total aerobic bacterial count	EN ISO 21149	EN ISO 21149
Yeasts and molds	EN ISO 16212	10 ¹ KBE/g
Pseudomonas aeruginosa	Ph. Eur. 2.6.13	Absence / 0.5 g
Staphylococcus aureus	Ph. Eur. 2.6.1	Absence / 0.5 g