

TECHNICAL DATA SHEET

ECO SUPERGEL "Superior Quality"

Water-soluble gel for diagnostic tests and therapies involving ultrasound systems

code	10171
packaging	bottle 260 gr. - 25 pcs./carton
producer	CERACARTA S.p.A

CE BRANDED



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Physical description	Water based viscous gel, light blue colour
Chemical composition	Water, polymer, humectant, preservatives, colouring agent
Preservatives	In accordance with Regulation EC 1223/2009
Colouring agents	In accordance with Regulation EC 1223/2009
Ph	6,2 ± 0,4
Density	1,02 gr/cm ³
Viscosity	80.000 ± 10.000 CPS (Brookfield viscometer, model DVI, spindle 6, 10 RPM, to 20°C)
Toxicity	A "REPETED PATCH TEST (96 Hours) " has been effected to get a valuation of the potential irritant power of a Medical Device and at preliminary level of the potential sensitive power of the same device. The checks made during and after the test noticed that none of the tester showed any sensibility or contact irritation or allergic reactions to all of the tests made.
Microbiological control	A " CHALLENGE TEST " has been made to check the efficacy of the preservative system. The controls which have been made have point out the suitability of the preservative system itself
Bottle	PEHD-PELD on rule D.M. 21-3-73 (alimentary use) and further amendments
Shelf life of the product	5 years for product preserved into original containers, sealed and preserved in dry and fresh environment. The a.m. gel are not subject to hydrolysis or to oxidations in the normal use conditions.
Use precautions	Being a non-flammable gel, non-corrosive and stable to the temperature , no particular precautions are required for its use