PRODUCT NAME	**0.9% ISOTONIC SODIUM CHLORIDE IRRIGATION SOLUTION** **PP BAGS 250 mL, 500 mL**
PRODUCT DESCRIPTION	Isotonic solution for surgical irrigation and cleansing. Tested for safe contact with tissue, bone and dentin for the extended time up to 24 hours. Single port, transparent and flexible polypropylene bag.
PHYSICAL CHARACTERISTICS	Sterile and non-pyrogenic. 100 ml contain: ▪ Sodium chloride 0.9 g, ▪ Water for injection qs. Sodium chloride pharmaceutical grade. Electrolyte densities: ▪ Na+ 154 mEq/L, ▪ Cl- 154 mEq/L. pH between 4.5 and 7.0. Single port suitable to be perforated by a closure-piercing device ISO 8536/4 compliant.
SAFETY INFORMATION	The device must only be used by qualified and trained personnel. Read the information on the label / IFU before use.
REFERENCE DIRECTIVES AND / OR STANDARDS	Directive 93/42/EC. Class IIa medical device. EN ISO 13485, EN ISO 14971, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 11737-1, EN ISO 11737-2, EN ISO 11607-1, EN ISO 11607-2, EN ISO 14644, EN 62366-1, EN 17141
STORAGE	Storage at room temperature between 15°C and 30°C. Keep out of the reach and sight of children.
STERILIZATION	Sterile, STEAM. The presence of drops of water inside the non-permeable sterile barrier is possible. They result from exposure to steam sterilization and do not pose a risk.
DISPOSAL	The device must be disposed of in accordance with medical procedures adopted by health care institutions and organizations and local, state or federal laws and regulations.
DURATION	The validity of the sterile device is 3 years. The expiration date indicated refers to the device in its intact and correctly stored package.
PACKAGES	REF 270631, bag 500 mL, box of 15 bags REF 270633, bag 250 mL, box of 20 bags

All technical information herein disclosed is provided to us by our raw material suppliers, under their own responsibility.