

BASE•128

250 ML SINGLE USE PRODUCT

SOLUTION FOR DECONTAMINATION OF HUMAN TISSUE INTENDED FOR TRANSPLANTATION

DECONTAMINATION

BASE•128	
Ingredients	Action
Glucose	energetic source
Amino acids, mineral salts, vitamins	nutrients
Gentamicin, Vancomycin, Cefotaxime and Amphotericin B	antibiotic/antifungal mixture
Hepes and bicarbonate	buffers
Purified water	solubilization of ingredients
Physical parameters	
Aspect	sterile liquid, pale yellow liquid when frozen, clear liquid after thawing and stirring
Hydrogenionic activity	7.20 - 7.60 pH unit
Osmolality	280 - 320 mOsm/kg
Microbiological parameters	
Endotoxins	tested according to EP and USP < 0.03 EU/ml < 20 EU/device according to USP
Mycoplasmas	absent, tested according to EP and USP
Sterilization	filtration with 0.1 µm filters and aseptic distribution according to EN 556-2 and EN ISO 13408-1
Packaging	tight-fitted PETG clear bottle with PE closure and seal
Volume	250 ml
Storage temperature	-25°C / -15°C
Expiry date	24 months
Intended use	decontamination of various human tissues intended for transplantation (cardiovascular, musculoskeletal, osteotendons, skin and amniotic membrane)
Class	medical device
CND Code	V9099
MD registration number	228841/R
Medical device class	Ila
CE mark	CE 0546

BASE•128 is a ready-to-use solution to decontaminate various human tissues intended for transplantation (cardiovascular, musculoskeletal, osteotendons, skin and amniotic membrane) in different conditions of time and temperature. The mixture of four antibiotics (vancomycin, gentamicin, cefotaxime, and amphotericin B desoxycholate) is active against the most frequent contaminants detected in tissue banks (Gram positive and Gram negative bacteria, yeasts and moulds). The BASE•128 decontamination solution can also be used for tissue transport to the bank, immediately after procurement, or during tissue dissection.

Ref.: BAS 005-00

Contents:

- ▶ 1 bottle of 250 ml
BASE•128
- ▶ 3 labels for product traceability
- ▶ 1 package insert

GS1-128 barcode

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