

## PRODUCT SPECIFICATION

Product Name	S <sub>IDA</sub> -HPMC 2%
Ref. No.	10011
Description	Hypromellose (HPMC) Ophthalmic Solution
Specification	20 mg of HydroxyPropyl Methylcellulose in a 2 mL pre-filled syringe
Intended Use	For use as an ophthalmic surgical aid in anterior segment surgical procedures, such as cataract extraction and intraocular lens implantation.
Features	Molecular weight: ~ 86,000 Daltons Viscosity: 3000 - 4500 cps at 27°C pH: 6.8 - 7.6 Osmolality: 250 - 350 mOsm/kg
Certification	CE <sub>2803</sub>
Classification	Class IIb, according to Annex IX of Council Directive 93/42/EEC
Sterilization Method	Steam
Conformity	MEDDEV 2.4/1 Rev. 9 - June 2010 Rule 8
Applicable Standards	ISO 9001, ISO 13485, ISO 14971, ISO 15798, ISO 11607, ISO 10993, ISO 17665, ISO 11138, ISO 11737, ISO 14644, ISO 14155, ISO 15223
Depiction	3—6
Primary Packing	Glass syringe
Secondary Packing	Individual pouch packing
Tertiary Packing	Paper box containing the syringe, an accompanying cannula and the Instructions for Use.