


Brand Name	SIDA-HPMC 2%
Ref. No.	10003; 10011
Description	Hypromellose (HPMC) Ophthalmic Solution
Specification	20 mg of HydroxyPropyl Methylcellulose
How Supplied	Prefilled glass syringe of 2 mL volume
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
Sterilization Method	Steam (solution); Ethylene oxide (accompanying cannula)
Certification	CE ₂₈₀₃
Classification	Class IIb, according to Annex IX of Council Directive 93/42/EEC
Conformity	MEDDEV 2.4/1 Rev. 9 - June 2010 Rule 8
Applicable Standards	ISO 13485, ISO 14971, ISO 15798, ISO 11607, ISO 10993, EN 62366, ISO 17665, ISO 11138, ISO 11737, ISO 14644, ISO 20417, EN 17141, ISO 14155, ISO 15223-1, ISO 24971
Depiction	
Primary Packing	Pre-filled syringe packed in blister; Viscoelastic Cannula packed in pouch.
Secondary Packing	Individual paper box containing the syringe, the accompanying cannula and set of labels for administrative use.
Instructions for Use	Available in electronic form (eIFU) via dedicated microsite.