

 SIDAPHARM® Ophthalmic & Medical Disposable Products	TECHNICAL DATA	SIDA-VISC DYAD Sodium Hyaluronate Ophthalmic Solutions Set
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Brand Name	SIDA-VISC DYAD
Description	 SIDA-VISC DYAD is a set of two individual Sodium Hyaluronate Ophthalmic Solutions. This set consists of a complete box of SIDA-VISC 1% and a complete box of SIDA-VISC 3%. Each box contains: 1x ophthalmic viscoelastic prefilled glass syringe of 1mL volume, packed in steam-sterilized blister. 1x ophthalmic cannula, angled, 25G or 27G, packed in an EO-sterilized pouch. - Product identification labels for administrative purposes.
Ref. No.	11030
General OVD Properties	Clear, colorless, odorless, sterile, isotonic solution. For intraocular use only. Not for injection. Origin: Biofermentation
Specific OVD Properties	SIDA-VISC 1%: 10mg/mL sodium hyaluronate ophthalmic solution. Molecular weight : 3.000.000 - 3.600.000 Dalton Viscosity : 20.000 - 70.000 mPa·s (cohesive) pH : 6.8 - 7.6 Osmolality : 270 - 400 mOsm/kg SIDA-VISC 3%: 30mg/mL sodium hyaluronate ophthalmic solution. Molecular weight : 1.100.000 - 2.000.000 Dalton Viscosity : 150.000 - 250.000 mPa·s (dispersive) pH : 6.8 - 7.6 Osmolality : 270 - 400 mOsm/kg
Intended Use	With their special viscoelastic properties, these solutions maintain a deep anterior chamber and protect the corneal endothelium throughout surgery.
Shelf life	3 years
Storage Conditions	2°C - 25°C
Certification	CE
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	EN ISO 9001:2015; EN ISO 13485:2016/AC: 2018; EN ISO 14971:2019; ISO 24971:2020; EN ISO 11607-1:2020; EN ISO 11607-2:2020; EN 556-1:2001/AC:2006; EN ISO 11737-1:2018; EN ISO 11737-2:2020; EN 62366-1:2015/A1:2020; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2021; EN ISO 10993-13:2010; EN ISO 10993-18:2020; EN ISO 15223-1:2021; ISO 20417:2021; EN ISO 15798:2022; ISO 11138-2:2017; ISO 14644-1:2015; ISO 14644-2:2015; ISO 14644-3:2019; ISO 14644-4:2022; EN ISO 17665-1:2006
Instructions for Use	Available in electronic form (eIFU) via dedicated microsite.