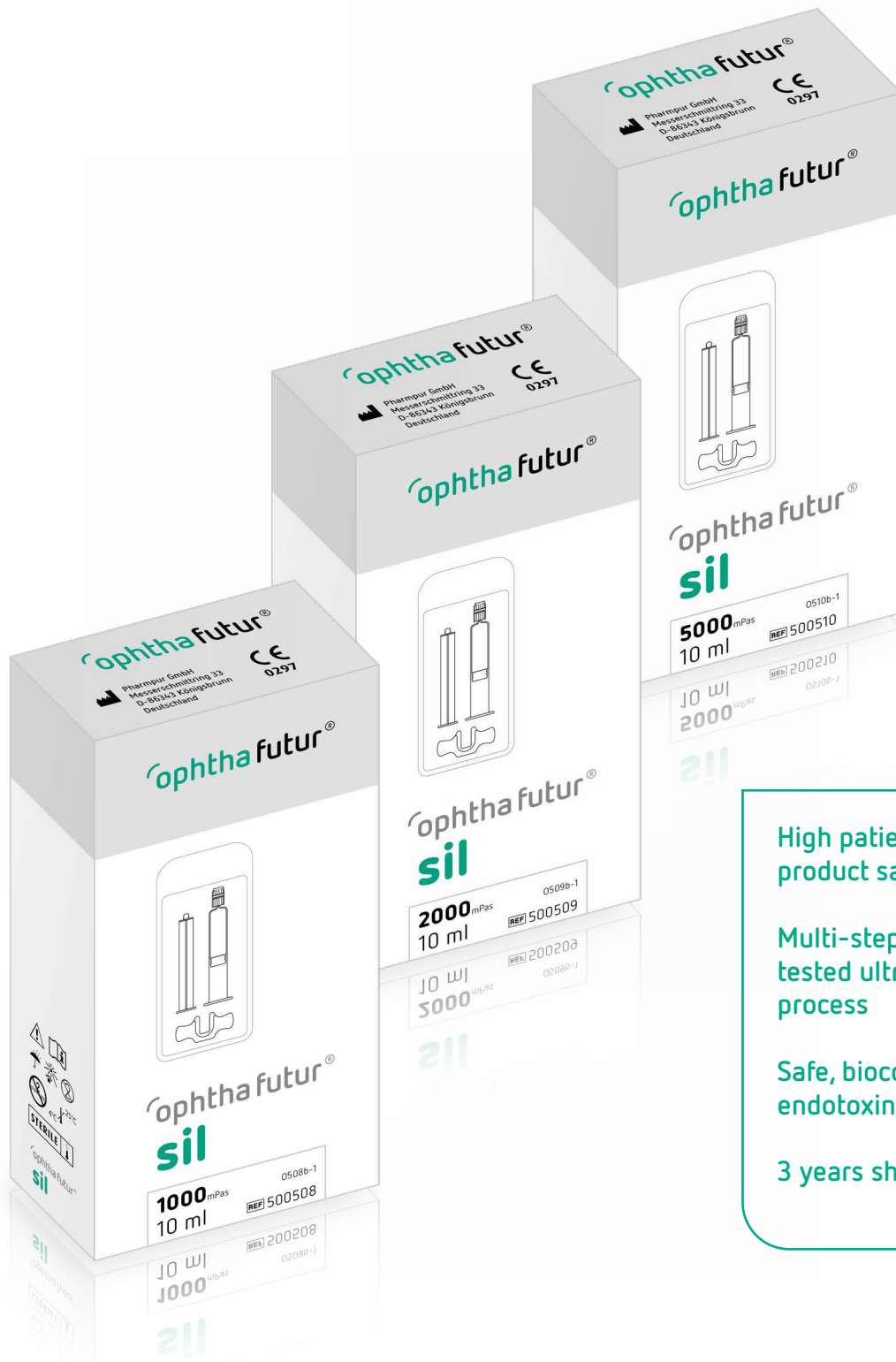


# ophtha futur<sup>®</sup> sil



High patient and product safety

Multi-step proven and tested ultra-purification process

Safe, biocompatible, sterile, endotoxin-free products

3 years shelf life

# ophthafutur<sup>®</sup> sil

## technical data-sheet

<b>Product Name</b>	ophthafutur <sup>®</sup> sil5000	ophthafutur <sup>®</sup> sil2000	ophthafutur <sup>®</sup> sil1000
Active compound	silicon oil	silicon oil	silicon oil

### Physical and Chemical Parameters

Viscosity (25 °C)	5,000 mPas	2,000 mPas	1,000 mPas
Density (25 °C)	0.97 g/cm <sup>3</sup>	0.97 g/cm <sup>3</sup>	0.97 g/cm <sup>3</sup>
Refractive Index nD25	1.404	1.404	1.404

### Chemical Control

Polydispersity (GPC)			
Specified Range	1.0 – 2.3	1.0 – 2.3	1.0 – 2.3
Typical Range	1.6 – 1.7	1.6 – 1.7	1.6 – 1.7
Content of Volatile Oligosiloxanes (HS-GC/MS)			
HMCTS/D3	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
OMCTS/D4	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
DMCPS/D5	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
DMCPS/D6	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MM/L2	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MDM/L3	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MD2M/L4	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
Σ	≤ 25 ppm	≤ 25 ppm	≤ 25 ppm

### Microbial control

Product Sterility ensured by	Heat Sterilization	Heat Sterilization	Heat Sterilization
Outer Surface Sterility ensured by	Steam Sterilization	Steam Sterilization	Steam Sterilization
Bacterial Endotoxins <sup>1</sup>	≤ 0.2 EU/ml	≤ 0.2 EU/ml	≤ 0.2 EU/ml

<sup>1</sup> LAL test acc. to EP 2.6.14/USP <85>

### Biocompatibility acc. to DIN EN ISO 10993

Cytotoxicity <sup>2</sup>	Non cytotoxic	Non cytotoxic	Non cytotoxic
Sensitization <sup>3</sup>	Non sensitizing	Non sensitizing	Non sensitizing
Irritation <sup>4</sup>	Non irritating	Non irritating	Non irritating

<sup>2</sup> Growth inhibition test of serum extract acc. to DIN EN ISO 10993-5:2009

<sup>3</sup> Murine Local Lymph Node Assay (LLNA) acc. to DIN EN ISO 10993-10:2010

<sup>4</sup> Acute eye-irritation on rabbits acc. to DIN EN ISO 10993-10:2010 Appendix B

### Presentation

	Filling Volume	Container	Sterile Barrier	Shelf Life
ophthafutur <sup>®</sup> sil5000	10 ml	Glass Syringe	Pouch	36 months
ophthafutur <sup>®</sup> sil2000	10 ml	Glass Syringe	Pouch	36 months
ophthafutur <sup>®</sup> sil1000	10 ml	Glass Syringe	Pouch	36 months

