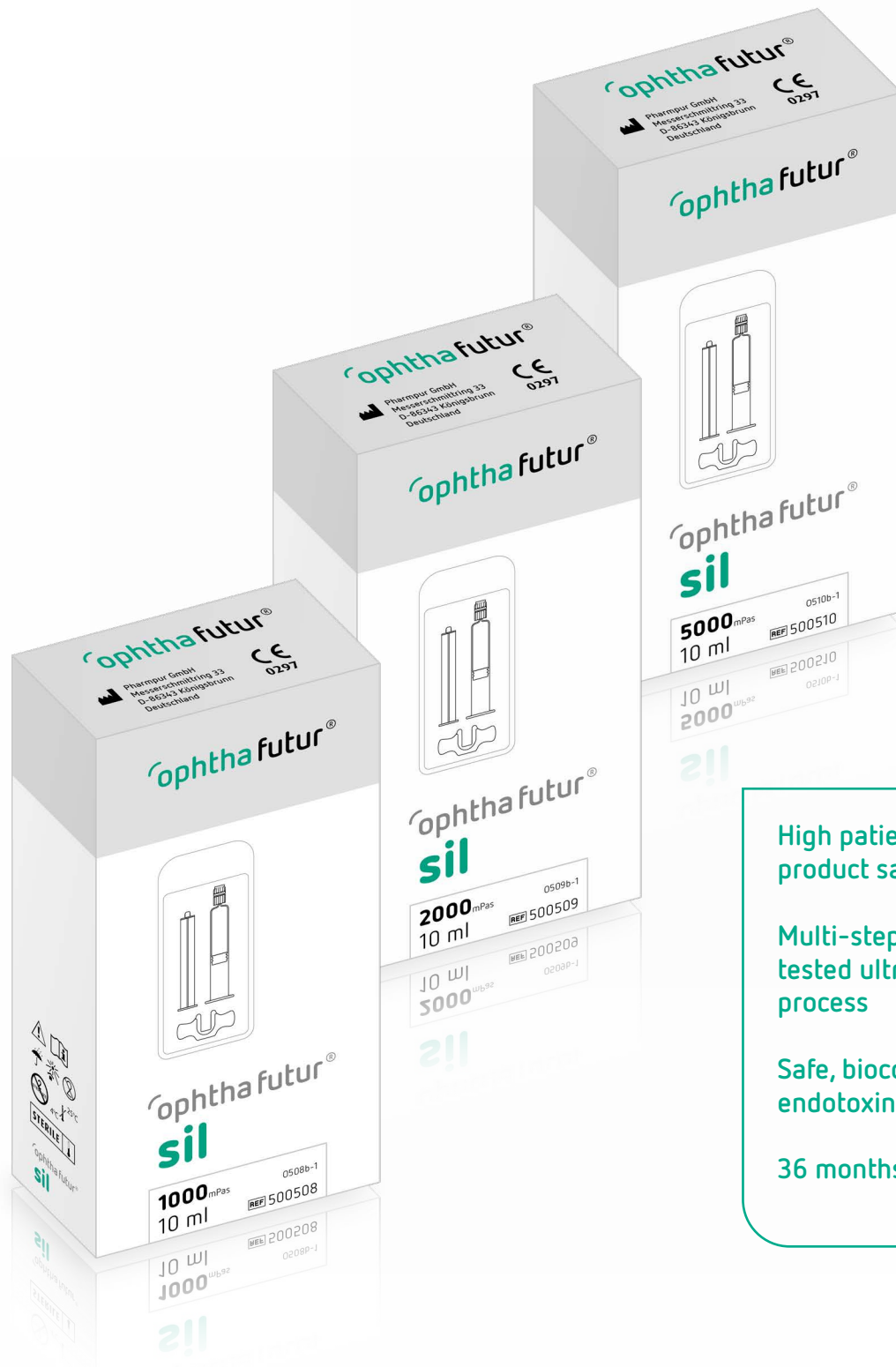


ophtha futur[®] sil



High patient and
product safety

Multi-step proven and
tested ultra-purification
process

Safe, biocompatible, sterile,
endotoxin-free products

36 months shelf life

ophthafutur[®] sil

technical data-sheet

Product Name

Active compound

ophthafutur[®] sil 5000

silicone oil

ophthafutur[®] sil 2000

silicone oil

ophthafutur[®] sil 1000

silicone oil

Physical and Chemical Parameters

Viscosity (25 °C)

5,000 mPas

2,000 mPas

1,000 mPas

Density (25 °C)

0.97 g/cm³

0.97 g/cm³

0.97 g/cm³

Refractive Index n_D25

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

DMCHS/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 Endotoxins¹

≤ 0.2 EU/ml

≤ 0.2 EU/ml

≤ 0.2 EU/ml

¹ LAL test acc. to EP 2.6.14/USP <85>

Biocompatibility acc. to DIN EN ISO 10993

Cytotoxicity²

Non cytotoxic

Non cytotoxic

Non cytotoxic

Sensitization³

Non sensitizing

Non sensitizing

Non sensitizing

Irritation⁴

Non irritating

Non irritating

Non irritating

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

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

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

Presentation

ophthafutur[®] sil5000

10 ml

Glass Syringe

Sterile Barrier

Pouch

Shelf Life

36 months

ophthafutur[®] sil2000

10 ml

Glass Syringe

Pouch

36 months

ophthafutur[®] sil1000

10 ml

Glass Syringe

Pouch

36 months

