

EU Quality Management System Certificate

We hereby certify the company

Albomed GmbH
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the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 8 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2025-06-06
Valid until 2026-11-29

Registration No. D1478800021
Report No. P25-00393-328817

Stuttgart, 2025-06-06



Notified Body



Devices:

9G-Visc 1.0% 1.0 ml
9G-Visc 1.4% 1.0 ml
9G-Visc 1.6% 1.0 ml
9G-Visc 1.8% 1.0 ml
9G-Visc 2.2% 1.0 ml
9G-Visc 3.0% 1.0 ml

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

an-bfh 1.6
an-bfh 1.8
an-bfh 2.2

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

Clear UltraHD 1.0
Clear UltraHD 1.4
Clear UltraHD 1.6
Clear UltraHD 1.8
Clear UltraHD 2.2
Clear UltraHD 3.0

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

EasyLuron 1.0%
EasyLuron 1.4%
EasyLuron 1.6%
EasyLuron 1.8%
EasyLuron 2.2%
EasyLuron 3.0%

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

HanitaVisco 1.0%
HanitaVisco 1.4%
HanitaVisco 1.6%
HanitaVisco 1.8%
HanitaVisco 2.2%
HanitaVisco 3.0%

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

i-Visc 1.0
i-Visc 1.4
i-Visc 1.6
i-Visc 1.8
i-Visc 2.2
i-Visc 3.0

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

myVisc Bio 1.4%
myVisc BioPlus 2.2%

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

Pe-Ha-Luron F 1.0%
Pe-Ha-Luron F 1.4%
Pe-Ha-Luron F 1.6%
Pe-Ha-Luron F 1.8%
Pe-Ha-Luron F 2.2%
Pe-Ha-Luron F 3.0%

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

Polyhyl 1.4
Polyhyl 1.6

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

Viscophta 100

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

ViscoSert F

Intended purpose: The viscoelastic properties allow lubrication, support and protection of the ocular tissue during eye surgery. It maintains the depth of the anterior chamber.

Risk class: IIb

9G-Gel 2.0%
9G-Gel 2.4%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

an-viscose 2.0%
an-viscose 2.4%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

avisena-visc 2.0%
avisena-visc 2.4%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

EasyVisc 2.0%
EasyVisc 2.4%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

Hypromel 2.4%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

i-Visc 2.0
i-Visc 2.4

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

myVisc Visco 2.0%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

Pe-Ha-Visco 2.0%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

Pe-Ha-Visco Plus 2.4%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

Polyvisc 2.0%
Polyvisc 2.4%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

ProGel 2.0%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

ViscoMed 2.0%
ViscoMed 2.4%

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

Viscophta 10

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

ViscoSert M

Intended purpose: As an adjuvant during surgical procedures on the anterior segment of the eye, it maintains the depth of the anterior chamber and protects the surrounding intraocular tissue. It supports the intraocular procedure due to its viscoelastic and wetting properties.

Risk class: IIb

Pe-Ha-Guard

Intended purpose: The viscoelastic solution is generally used for wetting the cornea during surgical procedures. In addition, it can be used as a lubricant and wetting agent during the implantation of hydrophilic acrylic lenses as well as hydrophobic acrylic or silicone lenses with commercially available injector and cartridge systems.

Risk class: IIb

The certificate is based on the previous certificate

D1478800009 (2022-01-19)

D1478800018 (2024-10-28)

with the following changes to D1478800018:

Supplemented by a new brand name and discontinuation of other brand names:

New brand name:

HanitaVisco 1.0%, 1.4%, 1.6%, 1.8%, 2.2%, 3.0% (Pe-Ha-Luron F)

Discontinuation of following brand names:

Visco 2.0%

Viscos 1.0%, 1.4%, 1.6%, 1.8%, 3.0%

Viscos 2.0% HPMC, Viscos 2.4% HPMC

Naluron 1.4, 1.6, 1.8

Hexavisc 1.0%, 1.4%, 1.6%, 1.8%, 3.0%

HiMed 1.4% 1.0 ml, HiMed 1.6% 1.0 ml