



Health Technology Certification

# EC-CERTIFICATE

## FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

### Grotex LLC

Russian Federation, 195279,  
Saint Petersburg,  
Industrialniy av. 71, bld. 2, lit. A

for design and manufacture of

### Liquid sterile and non-sterile medical products in the form of solutions and aerosols

*further details are given overleaf*

fulfills the requirements of Annex II excluding (4) of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class III devices covered by this certificate an EC Design Examination Certificate according to Annex II, Section 4 is required. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

For and on behalf of HTCert

GEORGE PAPPOUS  
Managing Director

FILIPPOS KOTTIS  
Certification Director

Certificate No: **1539C04201201**  
Issue Date: **10/12/2020**  
Original Approval: **10/12/2020**  
Valid until: **26/05/2024**  
References: **W001 1539 01**

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number 2803



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## Attachment to Certificate

No: 1539C04201201

Issued: 10/12/2020

### Devices / device categories included in the certificate

#### Class IIa devices:

- Gylan Comfort, moisturizing ophthalmic solution
- Gylan Ultra Comfort, moisturizing ophthalmic solution
- LinAqua forte, solution for washing and irrigation of the mouth and throat for children and adults, hypertonic concentration, aerosol
- LinAqua forte, solution for washing and irrigation of the nasal cavity for children and adults, hypertonic concentration, aerosol
- LinAqua baby, solution for washing and irrigation of the nasal cavity for children and adults, isotonic concentration, aerosol
- LinAqua norm, solution for washing and irrigation of the nasal cavity for children and adults, isotonic concentration, aerosol
- LinAqua soft, solution for washing and irrigation of the nasal cavity for children and adults, isotonic concentration, aerosol

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

A blue ink signature of George Pappous, written in a cursive style.

**FILIPPOS KOTTIS**  
Certification Director

A blue ink signature of Filippos Kottis, written in a cursive style.