



CERTIFICATION BODY
CERTIFICATION ASSOCIATION "RUSSIAN REGISTER"
ACCREDITATION CERTIFICATE OF THE FEDERAL
ACCREDITATION SERVICE № РОСС RU.0001.21ГА45

CERTIFICATE

This is to certify that the Quality Management System of

**Grotex Limited Liability Company
(Grotex LLC)**

71/2, Industrialny Ave., Lit. A, 195279, Saint Petersburg, Russia

has been assessed and found to be in accordance
with the requirements of

GOST ISO 13485-2017

in respect of development, production, packing, storage and distribution
of liquid sterile and non-sterile medical devices (solutions, aerosols,
gels, sprays, drops, injections)

No: 25.0549.026

Certificate Issue date: 18.11.2025

Revision number: 2

Certificate expiry date: 09.06.2028

Issue number: 1

Original date of the first certification cycle: 10.06.2025



The annex is an integral part of the certificate. The certificate covers only those sites of the company which are stated in this certificate. This certificate becomes invalid if conditions of certification are not fulfilled (<http://www.rusregister.ru/doc/004.00-105.pdf>).



GOST ISO 13485

РОСС RU.0001.21ГА45



СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM



Annex to the Certificate
№ 25.0549.026
of 18.11.2025

**Certification scope of management system of
Grotex Limited Liability Company (Grotex LLC)**

1. Kinds of activity: in respect of development, production, packing, storage and distribution of liquid sterile and non-sterile medical devices (solutions, aerosols, gels, sprays, drops, injections).
2. The requirements of p. 7.3.6 (in terms of a common interface or connecting to other devices); 7.3.7 (in terms of a common interface or connecting to other devices); 7.5.2 b), e); 7.5.3; 7.5.4; 7.5.10 GOST ISO 13485-2017 are not applicable to the certification scope of QMS.

Head of Certification Body

A. Vladimirtsev

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM



Annex to the Certificate
№ 25.0549.026
of 18.11.2025

**Certification scope of management system of
Grotex Limited Liability Company (Grotex LLC) includes:**

1. Production site 1

71/2, Industrialny Ave., Lit. A, 195279, Saint Petersburg, Russia

Kinds of activity: production and packing of liquid sterile and non-sterile medical devices (solutions, aerosols, gels, sprays, drops, injections).

2. Production site 2

13, Lapinsky Ave., bldg. 2, intracity municipality of the federal city of St. Petersburg, Rzhevka Municipal District, 195067, Saint Petersburg, Russia

Kinds of activity: production and packing of liquid sterile and non-sterile medical devices (solutions, aerosols, gels, sprays, drops, injections).

3. Development site

69, Revolution Highway, Lit. A, 195279, Saint Petersburg, Russia

Kinds of activity: development of liquid sterile and non-sterile medical devices (solutions, aerosols, gels, sprays, drops, injections).

4. Office site

27, Lvovskaya Str., 195176, Saint Petersburg, Russia

Kinds of activity: distribution of liquid sterile and non-sterile medical devices (solutions, aerosols, gels, sprays, drops, injections).

5. Warehouse

74/1, Marshala Blukhera Ave., bldg. 1, 195176, Saint Petersburg, Russia

Kinds of activity: storage of liquid sterile and non-sterile medical devices (solutions, aerosols, gels, sprays, drops, injections).

Head of Certification Body



A. Vladimirtsev