



CERTIFICATION BODY  
CERTIFICATION ASSOCIATION "RUSSIAN REGISTER"  
ACCREDITATION CERTIFICATE OF THE FEDERAL  
ACCREDITATION SERVICE № POCC RU.0001.21FA45

# 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

  
A. Vladimirtsev  
Head of Certification Body

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



Register of certificates  
<https://rusregister.ru/>

POCC RU.0001.21FA45

Certification Association "Russian Register": 101 Rimskogo-Korsakova Ave., 190121, Saint Petersburg, Russia

RUSSIAN REGISTER РУССКИЙ РЕГИСТР

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