



GUVERNUL  
REPUBLICII  
MOLDOVA



SERVICIUL FISCAL DE STAT



# CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.  
№ 1350048

Din  
От 10.01.2025 13:50



**DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ**

**Codul fiscal / Numărul de identificare**

Фискальный код / Идентификационный номер

1010600028048

**Denumirea**

Наименование

Societatea cu Răspundere Limitată BIOSISTEM MLD



**ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI  
INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ  
ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ  
СИСТЕМЫ**

**La data emiterii prezentului certificat restanța față de bugetul public național constituie**

На дату выдачи данной справки задолженность перед национальным публичным бюджетом составляет

0 MDL



**VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО**

25.01.2025 13:50



**Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответствии со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.**

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **10.01.2025 13:50**

**Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022**

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022



Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept ([mcabinet.gov.md](http://mcabinet.gov.md)) și este semnat electronic de către posesorul acestui portal și are aceeași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică ([msign.gov.md](http://msign.gov.md))

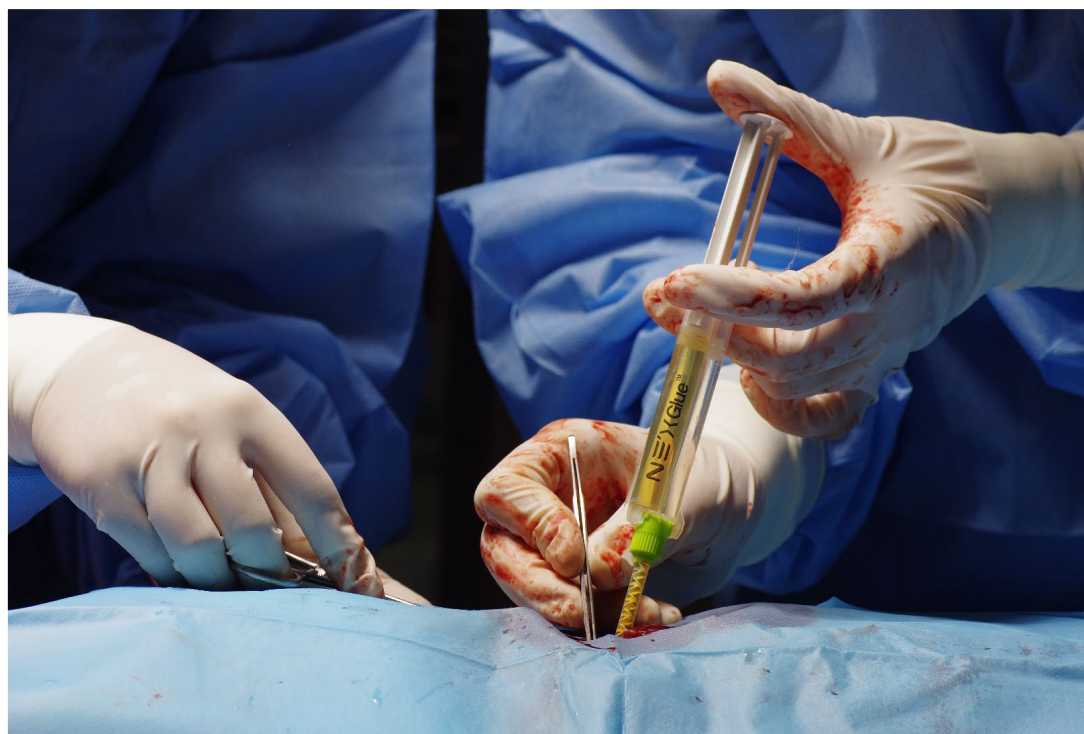
Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц ([mcabinet.gov.md](http://mcabinet.gov.md)) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Государственной Службой Электронной Подписью ([msign.gov.md](http://msign.gov.md))

# **NEX**Glue<sup>®</sup>

## Surgical Adhesive

Higher security, more opportunities

Full strength in **2 minutes**



PROVIDING SPECIALISTS WITH  
**INNOVATIVE**  
HEALTHCARE SOLUTIONS

WITH THE CENTRAL FOCUS ON  
PATIENTS' SAFETY AND USERS' COMFORT



## NE'X Glue<sup>®</sup> Surgical Adhesive

NE'X Glue<sup>®</sup> is two component surgical adhesive which covalently bonds with tissue and takes a form of flexible hydrogel. It also mechanically binds with synthetic materials. Such features allow for strong tissue - tissue or tissue - synthetic material connections.

Combination of Bovine Serum Albumin (BSA) and glutaraldehyde in optimal ratio with precise mixing inside the applicator of the delivery device allows for full consumption of glutaraldehyde during the polymerisation. As a result, absolutely biocompatible flexible hydrogel is created.



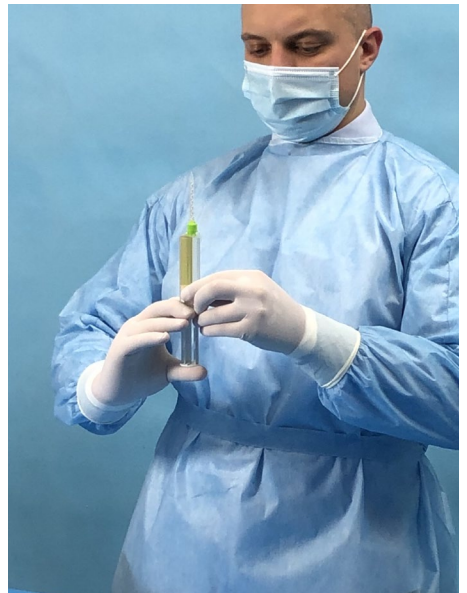
## KEY FEATURES:

- Variety of available volumes – 2, 5 and 10 ml
- Standard and spreader applicator tips
- Room temperature storage
- Ready for use in seconds
- Easy to use
- Full polymerization in 20-30 seconds
- Full strength in 2 minutes
- Works independently of the coagulopathic state of the patient
- Stronger than sealants based on fibrin or polyethylene glycols

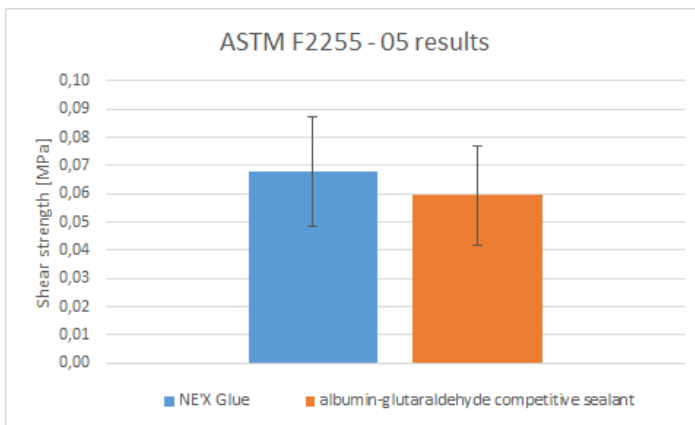
## CLINICAL APPLICATIONS:

NE'X Glue<sup>®</sup> is used as an adjunct to standard methods of repair such as sutures, staples, electrocautery and patches to seal, bond and reinforce tissue. Can be applied alone to fix surgical meshes, reinforce, repair or seal damaged parenchyma as a replacement of ineffective or impractical techniques.

- **VASCULAR SURGERY**
- **CARDIAC SURGERY**
- **THORACIC SURGERY**
- **GENERAL SURGERY**
- **GENITOURINARY SURGERY**
- **NEUROSURGERY**
- **ENT SURGERY**
- **SPINAL SURGERY**



REF	PRODUCT	CONTAINS
0206-NX2	NE'X Glue <sup>®</sup> Surgical Adhesive 2ml	5 single packs - each contains: 1 syringe (2ml) & syringe plunger, 4 syringe applicator tips
0206-NX5	NE'X Glue <sup>®</sup> Surgical Adhesive 5ml	5 single packs - each contains: 1 syringe (5ml) & syringe plunger, 4 syringe applicator tips
0206-NX10	NE'X Glue <sup>®</sup> Surgical Adhesive 10ml	5 single packs - each contains: 1 syringe (10ml) & syringe plunger, 4 syringe applicator tips
0206-NX4SM	Syringe applicator tip	10 single packs - each contains 4 syringe applicator tips
0206-NX3WM12	Syringe 12 mm spreader tip	10 single packs - each contains 3 syringe 12mm spreader tips
0206-NX3WM16	Syringe 16 mm spreader tip	10 single packs - each contains 3 syringe 16mm spreader tips



Endotoxin content in the whole extract [EU]	NE'X Glue <sup>®</sup> Surgical Adhesive	Albumin-glutaraldehyde competitive sealant
	0,290	0,535

**Grena Biomed Ltd.**  
Chelsea House, Chelsea Street,  
Nottingham, NG7 7HP, United  
Kingdom

**CUSTOMER SERVICE CENTER  
NOTTINGHAM OFFICE, UK**  
☎ + 44 115 9704 800  
☎ + 44 115 9704 800  
✉ export@grena.co.uk  
**www.grena.co.uk**





DECLARATION OF CONFORMITY/  
DEKLARACJA ZGODNOŚCI

Manufacturer /  
Wytwórca

Grena Biomed Limited  
Chelsea House, Chelsea Street,  
NG7 7HP Nottingham, Nottinghamshire,  
United Kingdom

Authorised representative /  
Autoryzowany przedstawiciel

MDML INTL LTD.  
10 McCurtain Hill Clonakilty,  
Co. Cork, P85 K230  
Republic of Ireland

Product /  
Produkt

NE`X Glue® Surgical Adhesive  
NE`X Glue® Klej chirurgiczny

REF numbers /  
Numery referencyjne

0206-NX2, 0206-NX5, 0206-NX10

Basic UDI-DI number/  
Basic UDI-DI kod

5060771920019F

Classification /  
Klasyfikacja

class III, Rule 17 according to Annex IX of the  
EC Directive 93/42/EEC

*We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Directive 93/42/EEC concerning medical devices which apply to them. The conformity assessment procedure was performed according to the Annex II including section 4 of the Directive 93/42/EEC and Regulation UE 2017/745 relating to post-market surveillance, market surveillance, vigilance, registration of economic operators. All supporting documentation is retained under the premises of the manufacturer, including Product Release Reports. In regards of bovine-derived material used for NE`X Glue Surgical Adhesive, we declare conformity with Commission Regulation (EU) No 722/2012 of 8 August 2012. /*

*Niniejszym na własną odpowiedzialność oświadczamy, że wyżej wymienione produkty spełniają wymagania Dyrektywy Rady 93/42/EWG dotyczącej wyrobów medycznych. Procedura oceny zgodności została przeprowadzona zgodnie z Załącznikiem II, sekcja 4 Dyrektywy Rady 93/42/EWG oraz Rozporządzenia Parlamentu Europejskiego i Rady (UE) 2017/745 dotyczące nadzoru po wprowadzeniu do obrotu, nadzoru rynku, obserwacji, rejestracji podmiotów gospodarczych..*

*Wszystkie wymagane dokumenty są przechowywane przez Wytwórcę, włączając raporty zwalniające wyroby. W odniesieniu do materiału pochodzenia bydłęcego używanego do kleju chirurgicznego NE`X Glue, deklarujemy zgodność z Rozporządzeniem Komisji (UE) nr 722/2012 z dnia 8 sierpnia 2012 r.*

**GRENA<sup>DG</sup>**

DECLARATION OF CONFORMITY/  
DEKLARACJA ZGODNOŚCI

Standards Applied / Zastosowane normy

All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Medical Device File.  
Wszystkie normy zharmonizowane wymagane przez Dyrektywę 93/42/EWG. Szczegółowa lista znajduje się w Dokumentacji wyrobu medycznego.

**CE** 1434

Notified Body /  
Jednostka notyfikowana

POLISH CENTRE FOR TESTING AND CERTIFICATION  
469 Puławska Street,  
02-844 Warsaw,  
Poland

EC Approval numbers /  
Numery zatwierdzenia EC

1434-MDD-080/2021  
1434-MDD-081/2021

Nottingham, 14.12.2022  
Rev.05

Iwona Michalska  
Quality Director

*Michalska Iwona*



# CERTIFICATE

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**EC Certificate No. 1434-MDD-080/2021**  
**EC Design-examination**  
**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the documentation submitted by:

**Grena Biomed Limited**  
**Chelsea House, Chelsea Street, NG7 7HP**  
**Nottingham, Nottinghamshire, United Kingdom**

related to the medical device, class III

**NE'X Glue<sup>®</sup> Surgical Adhesive**  
**Versions: 2ml, 5ml, 10ml**

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2021-02-10 to 2024-05-27

The date of issue of the Certificate: 2021-02-10



Issued under the Contract No. **MD-149/2019**  
Application No: 202/2019  
Certificate bears the qualified signature.  
Warsaw, 10/02/2021  
Module H1

**Anna Wyroba**  
**Vice-President**





# CERTIFICATE

**EC Certificate No. 1434-MDD-081/2021**  
**Full Quality Assurance System**  
**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**Grena Biomed Limited**

**Chelsea House, Chelsea Street, NG7 7HP**  
**Nottingham, Nottinghamshire, United Kingdom**

for the design, manufacture and final inspection of  
medical devices, class III

**NE'X Glue<sup>®</sup> Surgical Adhesive**  
**Versions: 2ml, 5ml, 10ml**

complies with requirements  
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)  
implemented into Polish law,  
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2021-02-10 to 2024-05-27

The date of issue of the Certificate: 2021-02-10



Issued under the Contract No. **MD-149/2019**  
Application No: 202/2019  
Certificate bears the qualified signature.  
Warsaw, 10/02/2021  
Module H2/3/4/5

**Anna Wyroba**  
**Vice-President**