



**Ministry of Health
of the Russian Federation**

**FEDERAL SERVICE ON SURVEILLANCE
IN HEALTHCARE (ROSZDRAVNADZOR)
DEPARTMENT FOR ORGANIZATION OF
STATE CONTROL AND REGISTRATION OF
MEDICAL PRODUCTS**

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Ref. date
No.: d



2373590

FSUE RFNC-VNIIEF

37, Mira pr., Sarov,
Nizhni Novgorod region, 347360

Notification of state registration of medical product

The Department for Organization of State Control and Registration of Medical Products of Roszdravnadzor informs that in accordance with clause 34 of the Rules of State Registration of Medical Products approved by Decree of the Government of the Russian Federation No. 1416 dated Dec 27, 2012, by Order of Roszdravnadzor No. 5271 dated Jun 22, 2020 the medical device "Unit for nitric oxide therapy AIT-NO-01 as per TU 32.50.21-001-07623615-2017", manufactured by FSUE RFNC-VNIIEF (Russia), has been registered in the Russian Federation with Registration Certificate No. RZN 2020/10977.

Appendix: 1. Copy of Expert Opinion - 11 sheets in 1 copy
2. Registration Certificate, original - 2 sheets in 1 copy

Head of Department

/signature/

Ye.M. Astapenko

Ye.V. Markova (expert Ye.S. Lobastova)
(499) 578 06 63

**MEDICAL PRODUCT
REGISTRATION CERTIFICATE**

No. RZN 2020/10977 dated June 22, 2020

For medical device

**Unit for nitric oxide therapy AIT-NO-01
as per TU 32.50.21-001-07623615-2017**

This Registration Certificate has been issued to

All-Russian Research Institute of Experimental Physics - Russian Federal Nuclear Center Federal State Unitary Enterprise (FSUE RFNC-VNIIEF), 37, Mira pr., Sarov, Nizhni Novgorod region, 607188, Russia

Manufacturer

All-Russian Research Institute of Experimental Physics - Russian Federal Nuclear Center Federal State Unitary Enterprise (FSUE RFNC-VNIIEF), 37, Mira pr., Sarov, Nizhni Novgorod region, 607188, Russia

The medical product manufacture site

FSUE RFNC-VNIIEF, building 6/21, building 6A/21, building 6B/21, industrial zone No.3, Sarov, Nizhni Novgorod region, 607188, Russia

Registration file No. **RD-22326/30184 dated May 30, 2018**

Medical product type **180790**

Class of potential risk of using medical product **2b**

Russian National Classification of Products by Economic Activities Code **32.50.21.112**

This Registration Certificate has an appendix on 1 sheet

by Order of Roszdravnadzor No. 5271 dated June 22, 2020
approved for usage on the territory of the Russian Federation

**Head of the Federal Service
on Surveillance in Healthcare**

/signature/

A.V. Samoylova

Seal: /Ministry of Health of the Russian Federation * FEDERAL SERVICE ON SURVEILLANCE IN HEALTHCARE (ROSZDRAVNADZOR)/

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APPENDIX
TO MEDICAL PRODUCT REGISTRATION CERTIFICATE
No. RZN 2020/10977 dated June 22, 2020

Sheet 1

For medical device

Unit for nitric oxide therapy AIT-NO-01
as per 32.50.21-001-07623615-2017:

- I. Composition:
- NO, NO2 monitoring unit;
 - generator;
 - electric unit;
 - purification unit;
 - neutralizer;
 - air supply unit;
 - stand with base;
 - handle for removing purification unit flask;
 - tubes for connection to breathing circuit, manufactured by Intersurgical Ltd., United Kingdom, RU No. FSZ 2009/03551 (if necessary).
- II. Accessories:
- monitoring unit bag;
 - fuse;
- II. Operational documentation:
- Operating Manual;
 - logbook.

**Head of the Federal Service on Surveillance in
Healthcare**

/signature/

A.V. Samoylova

Seal: /MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION * FEDERAL SERVICE ON
SURVEILLANCE IN HEALTHCARE (ROSZDRAVNADZOR)/

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