

FEDERAL SERVICE FOR SURVEILLANCE IN HEALTHCARE
(ROSZDRAVNADZOR)

**MARKETING AUTHORISATION
FOR MEDICAL DEVICE**

Dated May 22, 2025 No. RZN (P3H) 2021/15044

For the medical device

**COLLOST micro® collagen-based intradermal implant under technical specification TU
21.10.60-004-56533116-2019**

This Marketing Authorisation is issued to

**BioPHARMAHOLDING Limited Liability Company
(BioPHARMAHOLDING, LLC), Russia,
Bldg. 33, 18 Gamalei Str., Moscow, 123098**

Manufacturer

**BioPHARMAHOLDING Limited Liability Company
(BioPHARMAHOLDING, LLC), Russia,
Bldg. 33, 18 Gamalei Str., Moscow, 123098**

Place of medical device manufacture

See enclosure

Registration Dossier No. **RD(PD)-66832/108104 dated 28.01.2025**

Class of the potential risk of the medical device application **3**

Code of the All-Russian classifier of products by economic
activity types **21.10.60.191**

This Marketing Authorisation has the enclosure in 1 sheet

By Roszdravnadzor Order dated May 22, 2025 No. 3256

Permitted for circulation within the territory of the Russian Federation

**Deputy Head of the Federal Service for
Surveillance in Healthcare**

<Signed>

D.Yu. Pavliukov

Seal:

*MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION
FEDERAL SERVICE FOR SURVEILLANCE IN HEALTHCARE
PSRN 1047796244396
TIN 7710537160 * OKPO 00083960*

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**ENCLOSURE TO
MARKETING AUTHORISATION
FOR MEDICAL DEVICE**

Dated May 22, 2025 No. RZN (P3H) 2021/15044

Sheet 1

For the medical device

COLLOST micro® collagen-based intradermal implant under TU 21.10.60-004-56533116-2019, design options are the following:

I. COLLOST micro® collagen-based intradermal implant 0.05 g, set contains:

1. Micronized Type 1 Collagen – 0.05 g.
2. Patient information leaflet – 1 unit.
3. Sticker – 2 units.

II. COLLOST micro® collagen-based intradermal implant 0.15 g, set contains:

1. Micronized Type 1 Collagen – 0.15 g.
2. Patient information leaflet – 1 unit.
3. Sticker – 2 units.

III. COLLOST micro® collagen-based intradermal implant 0.45 g, set contains:

1. Micronized Type 1 Collagen – 0.45 g.
2. Patient information leaflet – 1 unit.
3. Sticker – 2 units.

Place of manufacture:

1. BioPHARMAHOLDING, LLC, 71 Revolutsii Str., Mosalsk, Kaluga Region, 249930, Russia.
2. BioPHARMAHOLDING, LLC, Bldg. 10, 18 Gamalei Str., Moscow, 123098, Russia.
3. Kaluga Scientific And Technical Enterprise "Corad", LLC, Est. 4, 1st Industrialnaya Str., Staromikhailovskoye Village, Borovsk District, Kaluga Region, 249010, Russia
4. AXENTER GROUP, LLC, Suite 6, 4 Technologicheskaya Str., Dubna Town urban district, Dubna Town, Moscow Region, 141981, Russia.
5. APTOS, LLC, Bldg. 1, 42 Bolshoi Blvd., Skolkovo Innovation Centre Territory, Moscow, 121205, Russia.
6. STERIPACK SERVICE, LLC, 10 Nauchny Passage, Moscow, 117246, Russia.

**Deputy Head of the Federal Service for
Surveillance in Healthcare**

<Signed>

D.Yu. Pavliukov

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