FEDERAL SERVICE FOR SURVEILLANCE IN HEALTHCARE
(ROSZDRAVNADZOR)

MARKETING AUTHORISATION FOR MEDICAL DEVICE

Dated October 17, 2022 No. FSR (ФСР) 2008/02112

For the medical device
COLLOST® collagen absorbable material for filling bone defects, contour plastic surgery of soft tissues and covering non-infected wound surfaces under technical specification TU 9393-001-56533116-2015

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(РД)-51851/66059 dated 05.09.2022**

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

Code of the All-Russian classifier of products by economic activity types **32.50.22.190**

This Marketing Authorisation has the enclosure on 1 sheet

By Roszdravnadzor Order dated October 17, 2022
No. 9957
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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FEDERAL SERVICE FOR SURVEILLANCE IN HEALTHCARE
(ROSZDRAVNADZOR)

ENCLOSURE TO MARKETING AUTHORISATION FOR MEDICAL DEVICE

Dated October 17, 2022 No. FSR (ФСР) 2008/02112

For the medical device
COLLOST® collagen absorbable material for filling bone defects, contour plastic surgery of soft tissues and covering non-infected wound surfaces under TU 9393-001-56533116-2015:

1. Membrane 15x15x0.2mm / 30x20x0.2 mm / 30x20x0.7 mm / 60x50x1.5 mm / 100x60x1.5 mm / 100x20x0.7mm/ 120x20x0.7 mm – 1 unit per vial / bottle / bag.
2. Tourniquet 50x5 mm – 1 unit per vial.
3. Bolus 8 mm – 2 units /4 units per vial.
4. Powder – 0.2 g / 0.5 g / 0.7 g /1.0 g / 2.0 g /10.0 g per vial/bottle.
5. Gel 7 % - 0.1 cm^3 / 0.5 cm^3 / 0.8 cm^3 / 1.0 cm^3 / 1.5 cm^3 / 2.0 cm^3 per syringe with stopper.
6. Gel 15 % - 0.1 cm^3 /1.0 cm^3 /1.5 cm^3 per syringe with stopper.

Place of manufacture:

1. BioPHARMAHOLDING, LLC, Bldg. 33, 18 Gamalei Str., Moscow, 123098, Russia.
2. BioPHARMAHOLDING, LLC, 71 Revolutsii Str., Mosalsk, Kaluga Region, 249930, Russia.
3. Utipado, LLC, Apt. 39-45, Suite I, Floor 2, Bldg. 1, 43 Ryabinovaya Str., 121471, Russia.

Deputy Head of the Federal Service for Surveillance in Healthcare *<Signed>* **D.Yu. Pavliukov**

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