

# UkrPharmExport LLC

Address: Sobornosti ave. 30-A, office 309-312, 02154, Kyiv, Ukraine;

Tel./Fax: (044) 502-54-87; (044) 451-44-80;

Web: www.ufe.com.ua; E-mail: arm@ufe.com.ua

## Certificate of quality No.7

Product Name	Sizes
<b>Medical hygroscopic hygienic cotton wool is non-sterile</b>	50g zig-zag
	100g zig-zag
	200g zig-zag

Manufacturer

UKRFARMEXPORT LLC

Declaration of conformity

from 02.02.2021"

Date of manufacture

2021-07

Expiration date

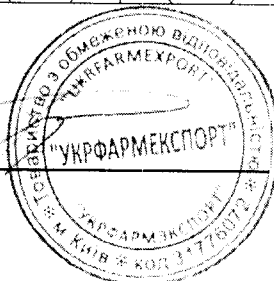
2027-07

Batch number (LOT)

07

No.	Name of indicators	Requirements of the ND			Measurement results
		50g	100g	200g	
1.	Composition	Cotton			Meets the requirements
2.	Description	Layers of white color, which consist of correctly placed fibers			Meets the requirements
3.	Clogging, %	1,50			Meets the requirements
4.	The presence of impurities: needles, splinters, etc...	Not allowed			Meets the requirements
5.	Humidity, %	8,0			Meets the requirements
6.	Ability to absorb, g	19			Meets the requirements
7.	Capillarity, mm	67			Meets the requirements
8.	Water extract reaction	Neutral			Meets the requirements
9.	Degree of linen for sterile cotton wool, %	66			Meets the requirements
10.	Scent	Not allowed			Meets the requirements
11.	Labeling and packaging	According to specifications			Meets the requirements
12.	Mass of cotton wool	50±4,0	100±5,0	200±9,0	Meets the requirements
13.	The size of the packed cotton wool	(80±10) x (190±15) x (50±5)	(90±10) x (280±15) x (50±5)	(110±10) x (350±15) x (70±5)	Meets the requirements

Director Khrushch Bohdan





# E.A.R.-CERTIFICATE

(ARTICLE 14.2 OF THE DIRECTIVE 93/42/EEC ON MEDICAL DEVICES)

REF. NO.: PD1086-2021

ORDER NO.: JC9477-2020

DATE: 25/03/2021

**MANUFACTURER:** UkrPharmExport LLC  
Sobornosti ave. 30-A  
Office 309-312,  
02154 Kyiv, Ukraine

**FACILITIES:** UkrPharmExport LLC  
Sobornosti ave. 30-A  
Office 309-312,  
02154 Kyiv, Ukraine

**PRODUCT CATEGORIES:** Please See Annex A - List of Devices (25 Devices, 8 Pages)

**MODELS:** Please See Annex A - List of Devices (25 Devices, 8 Pages)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 14.2 of the MDD 93/42/EEC and to the terms and conditions set out in the agreement entered into force on 01/05/2020.\*

Obelis s.a. - O.E.A.R.C.

Registered Address:

Bld General Wafis 53

1030 Bruxelles

Tel. +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO

Obelis sa



Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

\*This certificate is not a confirmation of product notification nor an approval to place products on the market.

\*\*This certificate will become void automatically upon termination of the EAR agreement.

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T: +32 (0) 2 732 5954 | F: +32 (0) 2 732 6003 | Email: mail@obelis.net | Website: www.obelis.net  
V3 - ID: 00453416 - 22/02/2019

\* This is not a CE mark and is only provided as a template for informational purposes



Order No.: JC9477-2020

Ref No.: PD1086-2021

**Annex A - List of Devices**

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN Code	Class	Rule
1.	N/A	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in roll	Cotton wool roll, non-sterile	For medical manipulation and hygienic care. Intended for use as ready-made dressings. Scope - treatment and prevention facilities and individual use.	58232	I	4
2.	N/A	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in roll	Cotton wool roll, non-sterile		58232	I	4
3.	N/A	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in zigzag tape	Cotton pleats		58234	I	4
4.	N/A	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in zigzag tape	Cotton pleats		58234	I	4
5.	N/A	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in perforated tape	Cotton wool roll, non-sterile		58232	I	4
6.	N/A	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in perforated tape	Cotton wool roll, non-sterile		58232	I	4

7.	N/A	Rivulet gauze bandage - Medical gauze bandage	Woven gauze roll, non-sterile	Intending: ready-made dressings and for the production of surgical dressings. Used as a fixing agent. Structure provides high hygroscopicity. Scope - treatment and prevention facilities and individual use.	48126 I	1
8.	N/A	Rivulet - Medical elastic bandage for fixation in tape	Pressure bandage, non-latex, non-sterile, reusable	The fixing bandage is used for fixing compresses, medical bandages, dressings of all types, cannulas, etc.	61223 I	1
9.	N/A	Rivulet - Medical elastic bandage in tape short stretch	Pressure bandage, non-latex, non-sterile, reusable	Prevention, improvement and treatment of varicose veins, chronic thrombophlebitis, support of joints and soft tissues at rest after injuries and operations.	61223 I	1
10.	N/A	Rivulet - Medical elastic bandage in tape medium stretch	Pressure bandage, non-latex, non-sterile, reusable		61223 I	1
11.	N/A	Rivulet - Medical elastic bandage in tape high stretch	Pressure bandage, non-latex, non-sterile, reusable		61223 I	1
12.	N/A	Rivulet - Medical elastic adhesive bandage in tape short stretch	Pressure bandage, non-latex, non-sterile, reusable	Intended for use during rehabilitation; sports medicine; neurology; pediatrics; military medical rehabilitation.	61223 I	1

13.	N/A	Rivulet - Bandage for fixation of the wrist joint	Wrist binder, reusable	Intended for use rehabilitation period after plaster bandage wearing or in case of ligamentous injury along with fixation of radiocarpal joint and thumb joint, in case of arthrosis, arthritis etc.	43817	I	1
14.	N/A	Rivulet - Supporting arm bandage	Pressure-management bandage, padded	Bandage used in fractures of hand, sprain and in the postoperative period.	58963	I	1
15.	N/A	Rivulet - Bandage medical prophylactic surgical elastic with edges of rigidity	Pressure bandage, non-latex, non-sterile, reusable	Bandage is used for osteochondrosis, radiculitis, landslides and hernias of intervertebral discs jamming nerve injures, chronic pain in the lumbosacral spine.	61223	I	1

16.	N/A	Rivulet - Bandage postoperative	Pressure bandage, non-latex, non-sterile, reusable	Bandage is shown at early immobilization after surgery for organs of abdominal cavity including caesarean section; prevention of formation of postoperative hernia the anterior abdominal wall (muscle weakness, after large cuts); strangulation prevention of postoperative hernia that can be set, linea alba hernias, umbilical hernias.	61223	1
17.	N/A	Rivulet - Knee joint bandage	Knee support/thermal therapy bandage	The knee joint bandage is applied in the following pathologies: arthritis, minor injuries and bruises, minor damage and sprains, synovitis, bursitis, as well as for the prevention of injuries and illnesses with physical exertion. It is used in the rehabilitation period, after wearing a plaster cast.	56282	1

18.	N/A	Rivulet - Knee joint Warming bandage	Knee support/thermal therapy bandage	A bandage is ensuring of the soft fixing and compression of knee-joint at traumas and damages of copulas, at the pains in a joint caused by arthritis, bursitis and synovitis.	56282 I	1
19.	N/A	Rivulet - Elastic bandage in the shape of eight for fixation of the ankle joint	Ankle binder, reusable	The bandage is used in ligamentous injury of an ankle joint and foot; rehabilitation period after plaster bandage wearing; prevention of dislocation or injuries during sporting activities; prevention of sprains of an ankle joint in persons who work hard; decrease of the loading on an ankle joint and Achilles' tension.	44481 I	1
20.	N/A	Rivulet - bandage pre / postnatal partum	Abdominal binder, reusable	The bandage is used to remove tension in the lumbar-sacral spine, reduces pain. Protects the abdominal wall tissue against excessive stretching.	47127 I	1

21.	N/A	Rivulet - Bandage Lumbar-sacral	Tubular support bandage, non-latex, reusable	<p>The bandage is used to easy fixing and stabilizing the lumbar spine as well as back muscles relax and anti-pain effect. The bandage is used for pain in the lumbar spine of various etiologies, osteochondrosis, spondylolisthesis including pain syndrome. Sciatica, myositis, bruising of the lumbar-sacral spine. Recovering from injuries and operations on the lumbar-sacral spine.</p>	61652 I	1
22.	N/A	Rivulet - Warming elastic belt	Tubular support bandage, non-latex, reusable	<p>The warming elastic belt is used in the treatment and prevention of neuritis, radiculitis, myositis. The product reduces the pain syndrome, removes muscle tension, and also speeds up the healing process. Due to the soft support, the use of the belt has a beneficial effect on the internal organs and improves the blood circulation.</p>	61652 I	1



23.	N/A	Rivulet - Posture corrector (reclinator) elastic with stiffening ribs	Wearable lumbar spine traction device	The bandage is used to the period of rehabilitation after injuries and operations on the thoracic spine; damage of posture in children and adults; spondylopathy and osteochondropathy of the thoracic spine; increased physical activity, forced long stay in a static position; middle and late periods of rehabilitation after injuries and operations on the lumbar spine.	61214	1
24.	N/A	Rivulet - Posture corrector (reclinator) elastic clavicular for children	Wearable lumbar spine traction device	The clavicular posture corrector is used for treatment and rehabilitation after injuries and operations on the upper thoracic spine, clavicle. Applied with kyphosis, kyphoscoliosis, pterygoid scapula and juvenile osteochondropathy, used in osteochondrosis of the upper thoracic spine, mild spondylopathy, osteoporosis.	61214	1

25.	N/A	Rivulet - Posture corrector (reclinator) elastic for collarbone	Wearable lumbar spine traction device	The clavicular posture corrector is used for treatment and rehabilitation after injuries and operations on the upper thoracic spine, clavicle. Applied with kyphosis, kyphoscoliosis, pterygoid scapula and juvenile osteochondropathy, used in osteochondrosis of the upper thoracic spine, mild spondylopathy, osteoporosis.	61214	I	1
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\* Annex A is part of the Agreement.

\*\* The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

**Obelis s.a.**

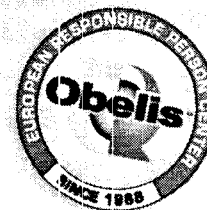
**Signature:**

**Stamp:**

**Date: 25/03/2021**

Obelis s.a. - OE.A.R.C.

Registered Address  
Bld Central Watius 57  
1030 Brussels  
Tel: +32 2 782 59 54 - Fax: +32 2 733 60 03



# CERTIFICATE OF MDD NOTIFICATION

Ref. No.: PD1101-2021

Date: 25/03/2021

Order No.: JC9477-2020

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 93/42/EEC WE, HERE AT OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: UKRPHARMEXPORT LLC

ADDRESS: SOBORNOSTI AVE. 30-A OFFICE 309-312, 02154 KYIV, UKRAINE

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the Class I \* devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations as per the Council Directive 93/42/EEC article 11 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical device(s), as stipulated here below, is/are fulfilling the applicable requirements of the Council Directive 93/42/EEC.

The notification of the following medical device(s) has been completed by Obelis s.a. (O.E.A.R.C.) on the 16/03/2021 in compliance with the Council Directive 93/42/EEC - article 14 requirements.

CLASS I MEDICAL DEVICE(S): PLEASE SEE ANNEX A - LIST OF DEVICES (8 PAGES, 25 DEVICES)

As of the 17/03/2020, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements\*\*, he therefore:

- Is required to affix the CE marking on these devices;
- May place these devices in the European Union and EEA territory.

Mr. G. Elkayam CEO  
Obelis sa



Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

\*Also applicable to Class Is and Im

\*\* This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

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V3 - ID: 00454516 - 22/02/2019

\* This is not a CE mark and is only provided as a template for informational purposes.



Order No.: JC9477-2020

Ref No.: PD1101-2021

**Annex A - List of Devices**

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMIDN Code	Class	Rule
1.	N/A	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in roll	Cotton wool roll, non-sterile	For medical manipulation and hygienic care. Intended for use as ready-made dressings. Scope - treatment and prevention facilities and individual use.	58232	I	4
2.	N/A	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in roll	Cotton wool roll, non-sterile		58232	I	4
3.	N/A	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in zigzag tape	Cotton pleats		58234	I	4
4.	N/A	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in zigzag tape	Cotton pleats		58234	I	4
5.	N/A	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in perforated tape	Cotton wool roll, non-sterile		58232	I	4
6.	N/A	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in perforated tape	Cotton wool roll, non-sterile		58232	I	4

7.	N/A	Rivulet gauze bandage - Medical gauze bandage	Woven gauze roll, non-sterile	Intending: ready-made dressings and for the production of surgical dressings. Used as a fixing agent. Structure provides high hygroscopicity. Scope - treatment and prevention facilities and individual use.	48126 I	1
8.	N/A	Rivulet - Medical elastic bandage for fixation in tape	Pressure bandage, non-latex, non-sterile, reusable	The fixing bandage is used for fixing compresses, medical bandages, dressings of all types, cannulas, etc.	61223 I	1
9.	N/A	Rivulet - Medical elastic bandage in tape short stretch	Pressure bandage, non-latex, non-sterile, reusable	Prevention, improvement and treatment of varicose veins, chronic thrombophlebitis, support of joints and soft tissues at rest after injuries and operations.	61223 I	1
10.	N/A	Rivulet - Medical elastic bandage in tape medium stretch	Pressure bandage, non-latex, non-sterile, reusable		61223 I	1
11.	N/A	Rivulet - Medical elastic bandage in tape high stretch	Pressure bandage, non-latex, non-sterile, reusable		61223 I	1
12.	N/A	Rivulet - Medical elastic adhesive bandage in tape short stretch	Pressure bandage, non-latex, non-sterile, reusable	Intended for use during rehabilitation; sports medicine; neurology; pediatrics; military medical rehabilitation.	61223 I	1

13.	N/A	Rivulet - Bandage for fixation of the wrist joint	Wrist binder, reusable	Intended for use rehabilitation period after plaster bandage wearing or in case of ligamentous injury along with fixation of radiocarpal joint and thumb joint, in case of arthrosis, arthritis etc.	43817	1	1
14.	N/A	Rivulet - Supporting arm bandage	Pressure-management bandage, padded	Bandage used in fractures of hand, sprain and in the postoperative period.	58963	1	1
15.	N/A	Rivulet - Bandage medical prophylactic surgical elastic with edges of rigidity	Pressure bandage, non-latex, non-sterile, reusable	Bandage is used for osteochondrosis, radiculitis, landslides and hernias of intervertebral discs jamming nerve injures, chronic pain in the lumbosacral spine.	61223	1	1

16.	N/A	Rivulet - Bandage postoperative	Pressure bandage, non-latex, non-sterile, reusable	Bandage is shown at early immobilization after surgery for organs of abdominal cavity including caesarean section; prevention of formation of postoperative hernia the anterior abdominal wall (muscle weakness, after large cuts); strangulation prevention of postoperative hernia that can be set, linea alba hernias, umbilical hernias.	61223	I	1
17.	N/A	Rivulet - Knee joint bandage	Knee support/thermal therapy bandage	The knee joint bandage is applied in the following pathologies: arthritis, minor injuries and bruises, minor damage and sprains, synovitis, bursitis, as well as for the prevention of injuries and illnesses with physical exertion. It is used in the rehabilitation period, after wearing a plaster cast.	56232	I	1

18.	N/A	Rivulet - Knee joint Warming bandage	Knee support/thermal therapy bandage	A bandage is ensuring of the soft fixing and compression of knee-joint at traumas and damages of copulas, at the pains in a joint caused by arthritis, bursitis and synovitis.	56282	I	1
19.	N/A	Rivulet - Elastic bandage in the shape of eight for fixation of the ankle joint	Ankle binder, reusable	The bandage is used in ligamentous injury of an ankle joint and foot; rehabilitation period after plaster bandage wearing; prevention of dislocation or injuries during sporting activities; prevention of sprains of an ankle joint in persons who work hard; decrease of the loading on an ankle joint and Achilles' tension.	44481	I	1
20.	N/A	Rivulet - bandage pre / postnatal parturn	Abdominal binder, reusable	The bandage is used to remove tension in the lumbar-sacral spine, reduces pain. Protects the abdominal wall tissue against excessive stretching.	47127	I	1



21.	N/A	Rivulet - Bandage Lumbar-sacral	Tubular support bandage, non-latex, reusable	The bandage is used to easy fixing and stabilizing the lumbar spine as well as back muscles relax and anti-pain effect. The bandage is used for pain in the lumbar spine of various etiologies, osteochondrosis, spondylolisthesis including pain syndrome. Sciatica, myositis, bruising of the lumbar-sacral spine. Recovering from injuries and operations on the lumbar-sacral spine.	61652	1	1
22.	N/A	Rivulet - Warming elastic belt	Tubular support bandage, non-latex, reusable	The warming elastic belt is used in the treatment and prevention of neuritis, radiculitis myositis. The product reduces the pain syndrome, removes muscle tension, and also speeds up the healing process. Due to the soft support, the use of the belt has a beneficial effect on the internal organs and improves the blood circulation.	61652	1	1

23.	N/A	Rivulet - Posture corrector (reclinator) elastic with stiffening ribs	Wearable lumbar spine traction device	The bandage is used to the period of rehabilitation after injuries and operations on the thoracic spine; damage of posture in children and adults; spondylopathy and osteochondropathy of the thoracic spine; increased physical activity, forced long stay in a static position; middle and late periods of rehabilitation after injuries and operations on the lumbar spine.	61214	1
24.	N/A	Rivulet - Posture corrector (reclinator) elastic clavicular for children	Wearable lumbar spine traction device	The clavicular posture corrector is used for treatment and rehabilitation after injuries and operations on the upper thoracic spine, clavicle. Applied with kyphosis, kyphoscoliosis, pterygoid scapula and juvenile osteochondropathy, used in osteochondrosis of the upper thoracic spine, mild spondylopathy, osteoporosis.	61214	1

25.				The clavicular posture corrector is used for treatment and rehabilitation after injuries and operations on the upper thoracic spine, clavicle. Applied with kyphosis, kyphoscoliosis, pterygoid scapula and juvenile osteochondropathy, used in osteochondrosis of the upper thoracic spine, mild spondylopathy, osteoporosis.			
	N/A	Rivulet - Posture corrector (reclinator) elastic for collarbone	Wearable lumbar spine traction device		61214	I	1

\* Annex A is part of the Agreement.


\*\* The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

**Obelis s.a.**

**Signature:**

**Stamp:**

**Date: 25/03/2021**

  
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 1030 Brussels  
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