

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

EC Declaration of Conformity

We, UkrPharmExport LLC, with address of Sobornosti ave. 30-A, office 309-312, 02154, Kyiv, Ukraine as manufacturer hereby declare under our sole responsibility that the products listed in Annex to this Declaration comply with the provisions of the Council Directive 93/42/EC.

The Manufacturer has designed the following authorized representative within the European Market:

Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
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E-mail: mail@obelis.net

The devices are Class I following Rule 1 and 4 of Annex IX of the Council Directive 93/42/EC.

The following conformity procedure has been applied in order to affix the CE marking on the devices:

Class 1: *the procedure referred to in Annex VII*

This Declaration is valid for all products bearing the CE marking placed on the European market as of the date of signature of this Declaration.

Kyiv, Ukraine

02/02/2021

Bohdan Khrushch
Director of UkrPharmExport LLC



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ANNEX TO EC DECLARATION OF CONFORMITY

List of Devices Covered by the Declaration of Conformity

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN Code	Class	Rule
1.	NA	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.	NA	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in roll	Cotton wool roll, non-sterile		58232	I	4
3.	NA	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in zigzag tape	Cotton pleats		58234	I	4
4.	NA	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in zigzag tape	Cotton pleats		58234	I	4
5.	NA	Rivulet Cotton Wool - Surgical absorbent medical cotton wool in perforated tape	Cotton wool roll, non-sterile		58232	I	4
6.	NA	Rivulet Cotton Wool - Hygienic absorbent medical cotton wool in perforated tape	Cotton wool roll, non-sterile		58232	I	4

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7.	NA	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.	NA	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.	NA	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.	NA	Rivulet - Medical elastic bandage in tape medium stretch	Pressure bandage, non-latex, non-sterile, reusable		61223	I	1
11.	NA	Rivulet - Medical elastic bandage in tape high stretch	Pressure bandage, non-latex, non-sterile, reusable		61223	I	1
12.	NA	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.	NA	Rivulet - Bandage for fixation of the wrist joint	Wrist binder, reusable	Intended for use as 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.	NA	Rivulet - Supporting arm bandage	Pressure-management bandage, padded	Bandage is used in fractures of hand, sprain and in the postoperative period.	58963	I	1

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15.	NA	Rivulet - Bandage medical prophylactic surgical elastic with edges of rigidity	Pressure bandage, non- latex, non- sterile, reusable	Bandage is used for osteocondrosis, radiculitis, landslides and hernias of intervertebral discs jamming nerve injuries, chronic pain in the lumbosacral spine.	61223	I	1
16.	NA	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.	NA	Rivulet - Knee joint Bandage	Knee support/thermal therapy bandage	The knee joint bandage is applied in the following pathologies: arthritis, arthrosis, deforming 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	I	1
18.	NA	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.	NA	Rivulet - Elastic bandage in the shape of eight for fixation of the ankle joint	Ankle binder, reusable	The bandage is used is 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' tendon.	44481	I	1
20.	NA	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.	47217	I	1

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21.	NA	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, lumbosacral spine spondylolisthesis including pain syndrome. Sciatica, myositis, bruising of the lumbar-sacral spine. Recovering from injures and operations on the lumbar-sacral spine.	61652	I	1
22.	NA	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	I	1
23.	NA	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	I	1
24.	NA	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	I	1
25.	NA	Rivulet - Posture corrector (reclinator) elastic for	Wearable lumbar spine traction device	The clavicular posture corrector is used for treatment and rehabilitation after injuries and operations on the upper thoracic	61214	I	1

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