

## EU DECLARATION OF CONFORMITY



(Medical elastic belts, spine support, posture correctors, recliners,  
bandages, braces, corsets, collars, arm supports and stabilizers)

*According to Article 19 of the Regulation (EU) 2017/745*

Name and address of the manufacturer: **SIA TONUS ELAST**  
**“Pilskalni”, Grinvalti, Nīcas pagasts., Dienvidkurzemes novads,**  
**LV-3473, Latvia, <https://lv.tonuselast.com/>**

Registration number: **40003264768**

*Declare that the EU Declaration of Conformity was issued under our sole responsibility and that the covered devices by the present declaration are in conformity with relevant provisions of Regulation (EU) 2017/745. The following medical devices meet the general safety and performance requirements set out in Annex I of the Regulation (EU) 2017/745.*

*Medical devices have been classified in risk class I according to the classification Rule 1 in Annex VIII of the Regulation (EU) 2017/745. A notified body is not involved in the conformity assessment procedure.*

Basic UDI	Article	Common Name of the Device
475028316203EPP021072	ELAST 0210	Medical elastic wrist brace with splint.
475028316204EPP02107M	ELAST 0210	Medical elastic wrist brace with splint.
475028317101EFR01102D	ELAST 0110	Medical orthopedic arm support.
475028317110FRUE0110-01DJ	ELAST 0110-01	Medical elastic orthopedic arm support with three-way support.
475028321100PET95096B	TONUS 9509	Warming medical elastic lumbar bandage.
475028321101PEBlacT95092Z	TONUS 9509	Warming medical elastic lumbar bandage.
475028320105T950901RQ	TONUS 9509-01	Warming medical elastic lumbar bandage.
475028321210PEAMT9509AMQA	TONUS 9509-AM	Warming medical elastic lumbar bandage with angora and merino wool.
475028321510PO-2E9901R8	ELAST 9901	Medical elastic postoperative abdominal belt.
475028321520PO-3E9901CE2	ELAST 9901 Comfort	Medical elastic postoperative abdominal belt with rigid back inserts.
475028321530POSE9901-01TR	ELAST 9901-01	Medical elastic postoperative belt for ostomy patients with an opening for attaching an ostomy bag.

475028321540PO4E9901LUXHW	ELAST 9901 LUX	Medical elastic postoperative abdominal belt with foam detail on the front of the belt and soft inside.
475028321550PO5E9901S5Q	ELAST 9901 SOFT	Medical elastic postoperative abdominal belt with foam detail on the front of the belt.
475028321560POAirE9901AB6	ELAST 9901 AIR	Medical elastic postoperative abdominal belt with rigid back inserts, from breathable and durable material.
475028321270PO3990102AIY5	ELAST 9901-02 AIR	Medical elastic postoperative abdominal belt with rigid back inserts from breathable and durable material, with double fixation.
475028321600PRE9902B6	ELAST 9902	Medical elastic rib belt for chest support.
475028321610PR2E9902-016G	ELAST 9902-01	Medical elastic thoracic belt with adjustable straps.
475028321620PR3E9914MW	ELAST 9914	Post-surgical breast stabilizer.
475028321400PE-2T0012K4	TONUS 0012	Medical elastic lumbar fixation corset.
475028321700PE3T0012-01U7	TONUS 0012- 01	Medical elastic lumbar fixation corset with stiff inserts and straps for regulating compression.
475028321710PE4T001201CXT	TONUS 0012- 01 Comfort	Medical elastic lumbar fixation corset with metal inserts and straps for regulating compression, reinforced.
475028321720PE5T001201L2G	TONUS 0012- 01 LUX	Medical elastic lumbar fixation corset with metal inserts and removable straps for regulating compression.
475028321730PEAT001201AAY	TONUS 0012- 01 AIR	Medical elastic lumbar fixation corset from breathable and durable material with stiff inserts and straps for regulating compression.
475028321740PE001202AIRJL	TONUS 0012- 02 AIR	Medical elastic lumbar fixation corset from breathable and durable material with metal inserts and straps for regulating compression, reinforced.
475028321800PGT0511B4	ELAST 0511	Medical elastic inguinal hernia belt with removable pads, double-sided.
475028321810PGPT0511-01NN	ELAST 0511-01	Medical elastic umbilical hernia belt with removable silicone pad.
475028321820PPDT0511D01SW	ELAST 0511D- 01	Medical elastic umbilical hernia belt with silicone pad, for children.
475028321831PS1E1604NV	TONUS 1604	Elastic medical support belt (suspensory).
475028322100KOE98063T	ELAST 9806	Medical elastic posture corrector.
475028322210KKLE0107CXZ	ELAST 0107 Comfort	Medical elastic thoracic spine support posture corrector.
475028322220KKLA0107AIR8J	ELAST 0107 AIR	Medical elastic thoracic spine support posture corrector from breathable and durable material.
475028322310KOL7E0108CNV	ELAST 0108 Comfort	Medical elastic thoracic spine support posture corrector with metal inserts.

475028322320KOLE010801CAH	ELAST 0108-01 Comfort	Medical elastic thoracic spine support posture corrector with metal inserts.
475028322330KO7010801AILH	ELAST 0108-01 AIR	Medical elastic thoracic spine support posture corrector from breathable and durable material with metal inserts.
475028322402KO8E0109F8	ELAST 0109	Medical elastic upper back brace with metal inserts.
475028322410KO9E0109-01U5	ELAST 0109-01	Medical elastic back brace for upper and lower spine with metal inserts.
475028322420KOL8E0109CRX	ELAST 0109 Comfort	Medical elastic upper back brace with metal inserts.
475028322430KOLE010901CDC	ELAST 0109-01 Comfort	Medical elastic back brace for upper and lower spine with metal inserts.
475028322440KO80109AIRBL	ELAST 0109 AIR	Medical elastic thoracic spine support posture corrector from breathable and durable material with metal inserts.
475028322700FKE17052Z	ELAST 1705	Clavicular reclinator for collarbone repositioning.
475028323300FSMT0411SG	ELAST 0411	Medical elastic cervical collar with soft fixation.
475028323310FSMDT0411D3X	ELAST 0411 D	Medical elastic cervical collar with soft fixation, for children.

**Intended purpose:**

Wrist brace is intended for rigid fixation and maintenance of the ligamentous (bone) apparatus and soft tissues of the hand at rest.

Arm support is designed for reliable and comfortable fixation of the hand during the rehabilitation period after fractures, sprains and surgical interventions.

Elastic arm support is used during the rehabilitation period after various injuries and diseases (in particular after a stroke), as well as after fractures, dislocations and other injuries.

Warming bandage is intended for the treatment and prevention of radiculitis and neuritis, as well as for preventing degenerative-dystrophic changes in the spine.

Postoperative belt is designed to support the abdominal muscles after surgery, with hernias, prolapse of the kidneys, as well as for women after childbirth.

Ostomy postoperative belt is designed to maintain the abdominal cavity after colostomy operations, and also provides comfortable care for the stoma.

Rib belt is designed to fix the chest, maintain internal organs in the pre- and postoperative periods, as well as to reduce pain.

Lumbar fixation corset is designed for displacement of the vertebral discs and instability of the spine.

Hernia belt is intended for conservative treatment of hernias and prevention of relapses after hernia repair. The bandage is also recommended for persons for whom surgical operations are contraindicated or not recommended.

Spine support is designed to prevent and eliminate postural disorders and curvature of the spine.

Clavicular reclinator is intended for fixation of the collarbone, as well as for the prevention and elimination of posture disorders in the upper thoracic spine.

Cervical collar designed to fix, stabilize and reduce the load in the cervical spine, as well as to normalize the tone of the neck muscles.

*Code GMDN* 13622, 41034, 41039, 41442, 41464, 47217, 47218, 46372, 64655, 62951

*CE marking date* 2004 (9509; 0411; 0012; 9901; 9902; 9806)  
2008(0210; 9509-AM; 0110; 0012-01; 0108 Comfort; 0109; 0107 Comfort; 9901 Comfort)  
2010 (0109-01; 9901-01; 0110-01;)  
2012 (0109 Comfort; ELAST 0109-01 Comfort; TONUS 0411D; TONUS 0511D-01;TONUS 0511-01)  
2015 (TONUS 0511; ELAST 9914; TONUS 1604; ELAST 0108-01 Comfort; ELAST 9902-01; ELAST 9901 Soft, ELAST 9901 LUX)  
2016 (TONUS 0012-01 LUX; TONUS 0012-01 Comfort; TONUS 0012-01 AIR; TONUS 0012-02 AIR; ELAST 0109 AIR; ELAST 0107 AIR; ELAST 0108-01 AIR; ELAST 9901 AIR; ELAST 9901-02 AIR; ELAST 1705)

*medical devices to which this declaration relates are in conformity with the following standard or normative documents:*

- Regulations of Minister Cabinet dd. 2017.11.28. Nr.689 "Procedures for Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices";
- On Medical Devices REGULATION (EU)2017/745 Annex VIII & CHAPTER III;
- TN LR 210301169-06-1998 Requirements for supports;

- LVS EN ISO 15223-1:2016 Medical devices Symbols to be used with medical device labels,  
labelling and information to be supplied;

"Pilskalni"

29.03.2023



Andis Paulins  
TONUS ELAST Member of  
the Board