

ALSFLU™

**Technical Report cited in Joint Ordinance No. 1 of January 23, 1996.
(Published in the Union Official Gazette No. 17, on January 24, 1996, Section I, Page 1118).**

In compliance with the categorization cited in Item 2 of Annex VI providing the information required by Items 1(a), 1(b), and 1(c) of the abovementioned Annex.

Information in the terms of the provisions of Article 37 of Decree No. 79.094/77

Request - Annex VI - Item I.1(a)

Detailed description of the product, including working principles and fundamentals and its action, technological characterization, content and composition, as applicable.

ALSFLU™ (**Hanging** Lumbosacral Extender) is a leather jacket (body harness) padded under the arm pits, sewn with resistant nylon, with 4 (four) horizontal adjustable buckling straps.

The upper part has two two-sided steel rings through which a nylon belt runs on each side, and a height adjustment device. The apparatus also has a PVC bar fixed by two leather straps, which allows the patient to hold on when suspended and a wooden board which serves as support while putting the jacket on.

ALSFLU™ measures about 57 cm long and 45 cm wide, depending on the biotype and sex of the patient. It can be ordered in sizes S, M, and L.

The jacket is suspended by the nylon straps from an iron bar at about 2 m from the floor. Its purpose during use is to enable the patient to remain suspended vertically with his/her feet 20 cm above floor level.

Request - Annex VI - Item I.1(b)

Indication, purpose or intended use of the product:

ALSFLU™ is indicated for patients afflicted with pathologies that affect the lumbar spine, such as disk hernias, degenerative diseases that cause lumbar pain, contracture of the posterior muscle of the spine.

It is intended to apply traction to the lumbosacral region vertebrae by suspending the patient by means of the jacket for an initial period of 1 minute, with rest intervals of 15 seconds (the time is gradually increased, according to the evolution of the clinical picture of the patient). The patient reports clinical improvement of the pain condition, as the patient's own weight produces a mechanic effect on the spine that allows the decompression of the affected nerve roots.

It is known today that 90% of the cases of disk hernia are not operated on, but rather treated conservatively with drugs, rest and physical therapy. ALSFLU™ has been developed seeking to afford non-invasive treatment of pathologies that affect the spine.

After medical release, the patient can continue ALSFLU™ prescribed exercises at home, after proper installation and following pre-established criteria for correct operation.

Request - Annex VI - Item I.1(c)

Precautions, restrictions, warnings, special care and clarification on the use, storage and transportation of the product.

ALSFLU™ can be used by individuals aged between 18 and 60, independently of race or sex, except those bearing systemic pathologies, acute cardiopathy, pregnant women after their 3rd

month of pregnancy, patients with congenital lumbosacral segment malformation and patients with CNS (central nervous system) disturbances.

Handling the jacket is easy and practical. It can be transported in a plastic bag without hazard to health or damage to the environment.