



INSTRUCTIONS FOR USE

Slide adapter	B12
---------------	-----

This product meets the technical requirements specified in Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, and it meets the requirements provided in Annex I – General safety and performance requirements, and in Annex VIII – Classification rules. The conformity is declared based on Article 52(7), Annex II, and Annex III of Regulation (EU) 2017/745.

INFORMATION

Date of issue: 2025-01-01

Date of last update: 2025-03-12

Please read this document carefully before using the product and observe the safety notices.

Report each serious incident related to the product to the manufacturer and to the relevant authority in your country.

Name of manufacturer: Elitex Prodexim SRL

Address of manufacturer: Ceuașu de Câmpie, str. Principală 7B, Mureș county, Romania

INDICATIONS

The loss, amputation, or deficiencies of the lower limbs.

There are no known contraindications.

DESCRIPTION

This product is intended for the construction of modular prostheses. Its use to assemble a prosthesis should be carried out in a specialized and approved facility by accordingly qualified personnel.

Combining the product with other parts in order to construct a prosthesis should only be done with parts or sub-assemblies designated for such purpose.

COMPOSITION

Material: aluminium ENAW 2007
threaded stud M8x14 DIN 913
screw M6x40 DIN 912
screw M5x20 DIN 912

GENERAL SAFETY INSTRUCTIONS

The medical personnel should provide the patient all the necessary information for the safe use of the device.

ASSEMBLY INSTRUCTIONS

1. Make sure all screws are correctly positioned and are screwed into the adapter.
2. Connect the adapter with adjustment core to the slide adapter.
3. Loosen the M6x40 screw in order to adjust the top part of the adapter.
4. Slide the top of the adapter into the correct position.
5. Insert the tube adapter into the clamp of the slide adapter, then tighten the screws.

Warning: Make sure that the tube adapter is fully inserted into the clamp before fastening.

Warning: For a secure fastening use a medium strength thread-locking adhesive (e.g. Loctite 243) and apply a torque of 10 Nm.

MAINTENANCE

The device and the whole prosthesis should be examined by a medical professional. The exam frequency should be determined based on the physical activity level of the patient.

CLEANING AND CARE

Clean with a wet cloth and mild soap. Dry with a cloth after washing.

WARNING

The weakening of the threaded assembly can lead to accidents. The maximum allowed bodyweight is 125 kg.