



INSTRUCTIONS FOR USE

Single-axis foot	LM-10
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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: polyurethane foam SHORE 65

beech wood

textile strap

aluminium ENAW 6082

GENERAL SAFETY INSTRUCTIONS

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

ASSEMBLY INSTRUCTIONS

1. Insert the single-axis foot adapter into the attachment site on the proximal part of the foot.
2. Insert the cushioning rubber.
3. Insert the nuts through the sole, and tighten them with a torque of 20 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.

Warning: In case the product got wet during use, it should be dried in order to prevent the deterioration of the wooden core.

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.

The product should be replaced after 24 months of use.