



INSTRUCTIONS FOR USE

Foam cover - transtibial	CE1
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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 used for the cosmetic covering of modular prosthesis. 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

GENERAL SAFETY INSTRUCTIONS

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

ASSEMBLY INSTRUCTIONS

Remove from the vacuum packaging two hours before use in order to restore original size.

Adjust the length and shape of the CE1 foam cover to the requirements of the assembled prosthesis.

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

Keep away from open flames and high temperatures as the material is flammable!