EU DECLARATION OF CONFORMITY

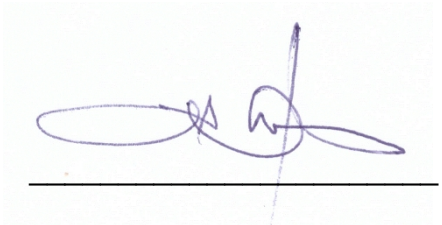
Elitex Prodexim SRL
Ceuasu de Campie, str. Principala, 7B,
jud. Mures, Romania
SRN: RO-MF-000033014

declares under his sole responsibility that the products in the category

Product category:	Prosthetic feet *The detailed product names and catalogue numbers are listed on page 2.*
Basic UDI-DI:	594476026ELTLFM000001M4
Product group:	External prostheses and orthoses
Intended Purpose:	Parts for lower extremity prostheses and orthoses

meets the applicable provisions as stated below and the relevant standards and common specifications as specified in the technical documentation.

Applicable regulations:	European Medical Device Regulation 2017/745
Risk class:	Class I (according to Annex VIII Medical Device Regulation 2017/745)
Conformity assessment procedure:	Art. 52(7) & Annex IV (Declaration of Conformity) according Regulation (EU) 2017/745 (MDR)
Notified body:	Not applicable
EU certificate:	Not applicable
Place, date:	Ceuasu de Campie, 10.02.2023



Ludovic-Zsolt Kantor, mech. eng.
Responsible person acc. MDR art.15

This Declaration of Conformity is valid until withdrawn or reissued due to significant product changes, new product codes or new/changed regulatory/legal requirement.

EU DECLARATION OF CONFORMITY

Versions:

Product name	Catalogue no.	UDI-DI
Solid ankle foot	LF-10	05944760260234
Single-axis foot	LM-10	05944760260241

This Declaration of Conformity is valid until withdrawn or reissued due to significant product changes, new product codes or new/changed regulatory/legal requirement.