

# EU DECLARATION OF CONFORMITY

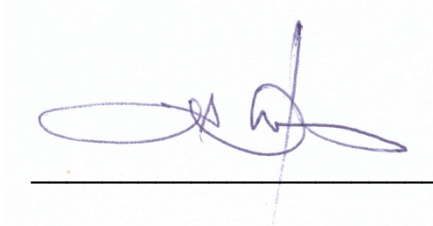
**Elitex Prodexim SRL**  
**Cevasu de Campie, str. Principala, 7B,**  
**jud. Mures, Romania**  
**SRN: RO-MF-000033014**

declares under his sole responsibility that the products in the category

Product category: Modular pieces for prosthetic leg  
*The detailed product names and catalogue numbers are listed on page 2.*  
Basic UDI-DI: 594476026ELTABCG00001EF  
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: Cevasu de Campie, 10.02.2023



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

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Versions:

<b>Product name</b>	<b>Catalogue no.</b>	<b>UDI-DI</b>
Lamination anchor with adjustment core for transtibial socket	A10	05944760260166
Lamination anchor with adjustment core for transfemoral socket	A11	05944760260111
Lamination anchor with rotatable adjustment core support	A20	05944760260128
Lamination anchor with rotatable adjustment core	A21	05944760260173
Socket adapter with adjustment core support	A30	05944760260180
Socket adapter with adjustment core	A31	05944760260012
Socket adapter with rotatable adjustment core support	A35	05944760260036
Socket adapter with rotatable adjustment core	A36	05944760260197
Eccentric adapter with adjustment core support	A37	05944760260074
Tube clamp adapter	B10	05944760260104
Slide adapter	B12	05944760260067
Double adapter	B30	05944760260029
Double adapter with adjustment core	B40	05944760260098
Tube adapter	B50	05944760260050
Foot adapter	C10	05944760260081
Single-axis knee joint (GEN10)	GEN10	05944760260135
Polycentric knee joint	GEN30	05944760260159
Single-axis knee joint (GEN40)	GEN40	05944760260142
Single-axis foot adapter	GLE10	05944760260043
Shuttle lock	SL	05944760260005

This Declaration of Conformity is valid until withdrawn or reissued due to significant product changes, new product codes or new/changed regulatory/legal requirement.