

EU DECLARATION OF CONFORMITY

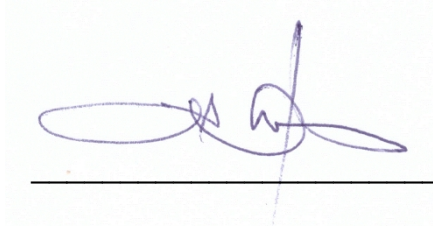
Elitex Prodexim SRL
Cevasu de Campie, str. Principala, 7B,
jud. Mures, Romania
SRN: RO-MF-000033014

declares under his sole responsibility that the products in the category

Product category: Orthoses
The detailed product names and catalogue numbers are listed on page 2.
Basic UDI-DI: 594476026ELTS00000001WP
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:

| Product name | Catalogue no. | UDI-DI |
|--|----------------------|----------------|
| Orthotic knee joint with lock | S3 | 05944760260210 |
| Polycentric knee joint with gear drive | S4 | 05944760260227 |
| Free-moving orthotic knee joint | S5 | 05944760260203 |

This Declaration of Conformity is valid until withdrawn or reissued due to significant product changes, new product codes or new/changed regulatory/legal requirement.