ETHNOCARE

WORK FORM		
Document Title	Document Description	Version No.
DOC-01	**DECLARATION OF CONFORMITY**	***10***

Ethnocare, Ethnocare Inc.,

Single Registration Number: CA-MF-000037257

500-240 Saint-Jacques Street, Montreal, QC, Canada, H2Y 1L9
Louis-Philippe Garneau
Admin@ethnocare.ca
+1 (418) 934-5669

We, Ethnocare Inc., located at 500-240 Saint-Jacques Street, Montreal, QC, Canada, H2Y 1L9, hereby declare under our own responsibility that the following products:

- Overlay
  - Basic UDI-DI: 628693190Overlay9J
  - Trademark: Overlay
  - Intended Purpose: The Overlay is a medical device used between the prosthetic liner and the exoprosthesis. The Overlay replaces socks ply added during the day due to a decreasing volume of the residual limb. The device intends to provide additional support for and volumetric fit of a tibial exoprosthesis.
  - Risk Class per EU MDR 2017/745: Class I non-sterile
  - Overlay variants:

Variants	Variants description
OV23-SH-L	Overlay size 23, short length, left version
OV23-SH-R	Overlay size 23, short length, right version
OV23-LG-L	Overlay size 23, long length, left version
OV23-LG-R	Overlay size 23, long length, right version
OV28-SH-L	Overlay size 28, short length, left version
OV28-SH-R	Overlay size 28, short length, right version
OV28-LG-L	Overlay size 28, long length, left version
OV28-LG-R	Overlay size 28, long length, right version
OV35-SH-L	Overlay size 35, short length, left version
OV35-SH-R	Overlay size 35, short length, right version
OV35-LG-L	Overlay size 35, long length, left version
OV35-LG-R	Overlay size 35, long length, right version

- Overlay TF
  - Basic UDI-DI: 628693190OVERLAYTF8S
  - Trademark: Overlay TF
  - Intended Purpose: The Overlay TF is a medical device used between the prosthetic liner and the exoprosthesis. The Overlay TF replaces socks ply added during the day due to a decreasing volume of the residual limb. The device intends to provide additional support for and volumetric fit of a transfemoral exoprosthesis.
  - Risk Class per EU MDR 2017/745: Class I non-sterile
  - Overlay TF variants:

Variants	Variants description
OVTF-32-SH-VAC	Overlay TF size 32, Short length, Distal vacuum suspension
OVTF-38-SH-VAC	Overlay TF size 38, Short length, Distal vacuum suspension
OVTF-40-SH-VAC	Overlay TF size 40, Short length, Distal vacuum suspension
OVTF-44-SH-VAC	Overlay TF size 44, Short length, Distal vacuum suspension
OVTF-48-SH-VAC	Overlay TF size 48, Short length, Distal vacuum suspension
OVTF-52-SH-VAC	Overlay TF size 52, Short length, Distal vacuum suspension
OVTF-32-LG-VAC	Overlay TF size 32, Long length, Distal vacuum suspension
OVTF-38-LG-VAC	Overlay TF size 38, Long length, Distal vacuum suspension
OVTF-40-LG-VAC	Overlay TF size 40, Long length, Distal vacuum suspension
OVTF-44-LG-VAC	Overlay TF size 44, Long length, Distal vacuum suspension
OVTF-48-LG-VAC	Overlay TF size 48, Long length, Distal vacuum suspension
OVTF-52-LG-VAC	Overlay TF size 52, Long length, Distal vacuum suspension
OVTF-32-SH-PIN	Overlay TF size 32, Short length, Distal pin and/or lanyard suspension
OVTF-32-LG-PIN	Overlay TF size 32, Long length, Distal pin and/or lanyard suspension
OVTF-32-XL-PIN	Overlay TF size 32, Extra Long length, Distal pin and/or lanyard suspension
OVTF-38-SH-PIN	Overlay TF size 38, Short length, Distal pin and/or lanyard suspension
OVTF-38-LG-PIN	Overlay TF size 38, Long length, Distal pin and/or lanyard suspension
OVTF-38-XL-PIN	Overlay TF size 38, Extra Long length, Distal pin and/or lanyard suspension
OVTF-40-SH-PIN	Overlay TF size 40, Short length, Distal pin and/or lanyard suspension
OVTF-40-LG-PIN	Overlay TF size 40, Long length, Distal pin and/or lanyard suspension
OVTF-40-XL-PIN	Overlay TF size 40, Extra Long length, Distal pin and/or lanyard suspension
OVTF-44-SH-PIN	Overlay TF size 44, Short length, Distal pin and/or lanyard suspension
OVTF-44-LG-PIN	Overlay TF size 44, Long length, Distal pin and/or lanyard suspension
OVTF-44-XL-PIN	Overlay TF size 44, Extra Long length, Distal pin and/or lanyard suspension
OVTF-48-SH-PIN	Overlay TF size 48, Short length, Distal pin and/or lanyard suspension
OVTF-48-LG-PIN	Overlay TF size 48, Long length, Distal pin and/or lanyard suspension

OVTF-48-XL-PIN	Overlay TF size 48, Extra Long length, Distal pin and/or lanyard suspension
OVTF-52-SH-PIN	Overlay TF size 52, Short length, Distal pin and/or lanyard suspension
OVTF-52-LG-PIN	Overlay TF size 52, Long length, Distal pin and/or lanyard suspension
OVTF-52-XL-PIN	Overlay TF size 52, Extra Long length, Distal pin and/or lanyard suspension

- Underlay
  - Basic UDI-DI: 62844828UNDERLAYH3
  - Device Family: Underlay
  - Device Trade names: Underlay Transtibial Open-toe, Underlay Transtibial Close-toe, Underlay Transfemoral Open-toe, Underlay Transfemoral Close-toe
  - Intended Purpose: The Underlay purpose is to manage perspiration and moisture accumulation at the skin-liner interface. By acting as a textile interface between the skin and the liner, the Underlay helps absorb and transfer sweat away from the skin, thereby reducing relative humidity inside the liner.
  - Risk Class per EU MDR 2017/745: Class I non-sterile
  - Underlay variants:

Variants	Variants description
UDTT-23-SH	Underlay Transtibial size 23, Short length, Open-toe
UDTT-23-SH-C	Underlay Transtibial size 23, Short length, Close-toe
UDTT-28-SH	Underlay Transtibial size 28, Short length, Open-toe
UDTT-28-SH-C	Underlay Transtibial size 28, Short length, Close-toe
UDTT-35-SH	Underlay Transtibial size 35, Short length, Open-toe
UDTT-35-SH-C	Underlay Transtibial size 35, Short length, Close-toe
UDTT-23-MD	Underlay Transtibial size 23, Medium length, Open-toe
UDTT-28-MD	Underlay Transtibial size 28, Medium length, Open-toe
UDTT-35-MD	Underlay Transtibial size 35, Medium length, Open-toe
UDTT-23-LG	Underlay Transtibial size 23, Long length, Open-toe
UDTT-23-LG-C	Underlay Transtibial size 23, Long length, Close-toe
UDTT-28-LG	Underlay Transtibial size 28, Long length, Open-toe
UDTT-28-LG-C	Underlay Transtibial size 28, Long length, Close-toe
UDTT-35-LG	Underlay Transtibial size 35, Long length, Open-toe
UDTT-35-LG-C	Underlay Transtibial size 35, Long length, Close-toe
UDTT-23-XL	Underlay Transtibial size 23, Extra-long length, Open-toe
UDTT-28-XL	Underlay Transtibial size 28, Extra-long length, Open-toe
UDTT-35-XL	Underlay Transtibial size 35, Extra-long length, Open-toe
UDTF-32-SH	Underlay Transfemoral size 32, Short length, Open-toe
UDTF-32-MD	Underlay Transfemoral size 32, Medium length, Open-toe

ETHNOCARE

WORK FORM		
Document Title	Document Description	Version No.
DOC-01	**DECLARATION OF CONFORMITY**	***10***

UDTF-32-LG	Underlay Transfemoral size 32, Long length, Open-toe
UDTF-40-SH	Underlay Transfemoral size 40, Short length, Open-toe
UDTF-40-MD	Underlay Transfemoral size 40, Medium length, Open-toe
UDTF-40-LG	Underlay Transfemoral size 40, Long length, Open-toe
UDTF-48-SH	Underlay Transfemoral size 48, Short length, Open-toe
UDTF-48-MD	Underlay Transfemoral size 48, Medium length, Open-toe
UDTF-48-LG	Underlay Transfemoral size 48, Long length, Open-toe
UDTF-32-SH-C	Underlay Transfemoral size 32, Short length, Close-toe
UDTF-32-MD-C	Underlay Transfemoral size 32, Medium length, Close-toe
UDTF-40-SH-C	Underlay Transfemoral size 40, Short length, Close-toe
UDTF-40-MD-C	Underlay Transfemoral size 40, Medium length, Close-toe
UDTF-48-SH-C	Underlay Transfemoral size 48, Short length, Close-toe
UDTF-48-MD-C	Underlay Transfemoral size 48, Medium length, Close-toe

meet the provisions of the (EU) MDR 2017/ including Annex IV (II & III) and the general safety and performance requirements which apply to them.

The above-mentioned device(s) have been classified as a class I device according to rule 1 of medical directives MDR 2017/745.

This Declaration is valid for all products concerned bearing the CE mark and manufactured by the above entitled "Manufacturer".

Name	Title	Signature	Date
Olivier Parent	Person Responsible for Regulatory Compliance	Olivier Parent	15-06-2026

European Authorized Representative:
Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem,
The Netherlands
Email: EmergoEurope@ul.com
Tel: +31 (0) 70 345-8570
SRN: NL-AR-000000116