

Declaration of Conformity

for the Two Layer Compression (TLC) Elastic Bandage, Non-Latex Family
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
concerning Medical Devices.

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them, and the CE Mark may be affixed.

General Product Name:	Two Layer Compression (TLC) Elastic Bandages, Non-Latex
Legal Manufacturer: (Name on Label)	Andover Healthcare, Inc (a subsidiary of OVIK Health Products LLC) 9 Fanaras Drive Salisbury, MA 01952 USA
Manufacturers SRN:	US-MF-000035055
Basic UDI-DI:	0724004610675PG
Variants:	See Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	CoFlex/AndoFlex/Unna Boot Two Layer Compression (TLC) bandages are designed to help treat venous leg ulcers and other related conditions.
MDR Classification:	Class I [Rule 1 and 4]
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name Genoa Atwood **Position** Regulatory Affairs Manager

Signed  **Date** 04-SEP-2024 **Place** USA

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on their behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

Appendix II – Product Listing/Schedule

Catalogue #	Description (TLC = Two Layer Compression)	GMDN	EMDN
ASP-7805TLC-TN	AndoFlex TLC W/Individual 4"	58983	M03040299
ASP-7805TLC-XL	AndoFlex TLC XL W/Individual 4"	58983	M03040299
ASP-7807TLC-TN	AndoFlex TLC Lite W/Individual 4"	58983	M03040299
ASP-7905TLC-TN	AndoFlex TLC LS STD	58983	M03040299
ASP-7907TLC-TN	AndoFlex TLC LS LITE	58983	M03040299
ASP-UB830C-01	ANDOFLEX UBC SINGLE 3"	58983	M03040299
ASP-UB830Z-01	ANDOFLEX UBZ SINGLE 3"	58983	M03040299
ASP-UB840C-01	ANDOFLEX UBC SINGLE 4"	58983	M03040299
ASP-UB840Z-01	ANDOFLEX UBZ SINGLE 4"	58983	M03040299
ASP-8830UBC-SC	AndoFlex CAL STD 3"	58983	M03040299
ASP-8830UBC-TN	AndoFlex UBC W/IND 3"	58983	M03040299
ASP-8830UBZ-SC	AndoFlex ZINC STD 3"	58983	M03040299
ASP-8830UBZ-TN	ANDFLEX UBZ W/IN TN	58983	M03040299
ASP-8840UBC-SC	AndoFlex CAL STD 4"	58983	M03040299
ASP-8840UBC-TN	AndoFlex UBC W/IN 4"	58983	M03040299
ASP-8840UBZ-SC	AndoFlex ZINC STD 4	58983	M03040299
ASP-8840UBZ-TN	ANDOFLEX UBZ NL TAN 4	58983	M03040299
7800TLC-02	CoFlex TLC LT.BL Standard Single Tan 2", 2Rolls	58983	M03040299
7800TLC-06	CoFlex TLC Standard Single Tan/LB, 6", 2Rolls	58983	M03040299
7800TLC-TN	CoFlex TLC Standard Tan/LB W/Individual 4"8-2Rolls	58983	M03040299
7800TLC-XL	CoFlex TLC XL Standard Tan/LB 4" 8-2R	58983	M03040299
7800TN-06	CoFlex TLC Standard Tan/LB, 6", 2R	58983	M03040299
7800TN-12	CoFlex TLC Layer1 Foam 2"X1.3YD 32Rolls	58983	M03040299
7800TN-13	CoFlex TLC Layer1 Foam 3"X3YD 18Rolls	58983	M03040299
7800TN-14	CoFlex TLC Layer1 Foam 4"X3.8YD 18Rolls	58983	M03040299
7800TN-16	CoFlex TLC Layer1 Foam 6"X3.8YD 10Rolls	58983	M03040299
7800TN-22	CoFlex TLC Standard Layer 2 2"X3YD 32Rolls	58983	M03040299
7800TN-24	CoFlex TLC Standard Layer 2 4"X5YDS 32Rolls	58983	M03040299
7800TN-26	CoFlex TLC Standard Layer 2 6"X5YD 15Rolls	58983	M03040299
7802TLC-TN	CoFlex TLC Lite Tan/LB W/Individual 4"8-2Rolls	58983	M03040299
7802TLC-06	CoFlex TLC Lite Tan/LB, 6", 2R	58983	M03040299
7802TN-14	CoFlex TLC Layer1 Foam 4"X3YD 10Rolls	58983	M03040299
7802TN-16	CoFlex TLC Layer1 Foam LB 6"X3YD 10Rolls	58983	M03040299
7802TN-21	CoFlex TLC Lite Layer2 1"X3.8YD 36	58983	M03040299
7802TN-22	CoFlex TLC Lite Layer2 2"X3.8YD 32Rolls	58983	M03040299
7802TN-24	CoFlex TLC Lite Layer2 4"X3.8YD 32Rolls	58983	M03040299

7802TN-26	CoFlex TLC Lite Layer2 6"X3.8YDS 15Rolls	58983	M03040299
7900TLC-TN	CoFlex TLC Long Stretch Standard Tan/LB 4"8-2Rolls	58983	M03040299
7902TLC-TN	CoFlex TLC Long Stretch Lite Tan/LB 4" 8-2Rolls	58983	M03040299
8830UBC-SC	Unna Boot Calamine Standard W/Individual Tan/PK 3" 8K	58983	M03040299
8830UBC-TN	Unna Boot Calamine Non-Latex W/Individual Tan/PK 3" 8K	58983	M03040299
8840UBC-SC	Unna Boot Calamine Standard W/Individual Tan/PK 4" 8K	58983	M03040299
8840UBC-TN	Unna Boot Calamine Non-Latex W/Individual Tan/PK 4" 8K	58983	M03040299
UB830C-01	Unna Boot Calamine PK Single Rolls 3"X6 12Rolls	58983	M03040299
UB840C-01	Unna Boot Calamine PK Single Rolls 4"X6 12Rolls	58983	M03040299
8830UBZ-SC	Unna Boot Zinc Standard W/Individual Tan/WH 3" 8K	58983	M03040299
8830UBZ-TN	Unna Boot Zinc Non-Latex W/Individual Tan/WH 3" 8K	58983	M03040299
8840UBZ-SC	Unna Boot Zinc Standard W/Individual Tan/WH 4" 8K	58983	M03040299
8840UBZ-TN	Unna Boot Zinc Non-Latex W/Individual Tan/WH 4" 8K	58983	M03040299
UB830Z-01	Unna Boot Zinc WHT Single Rolls 3"X6 12	58983	M03040299
UB840Z-01	Unna Boot Zinc WHT Single Rolls 4"X6 12	58983	M03040299

Version History

Version	Compiled by	Date	Description
1.0	G. Atwood	23JUN2022	New Document for EU 2017/745 compliance
2.0	G. Atwood	09FEB2023	Addition of 7800TN-06
2.1	G. Atwood	28APR2023	Addition of 7802TLC-06
2.2	G. Atwood	28-SEP-2023	Addition of SRN
3.0	G. Atwood	01-JUL-2024	Add Andoflex codes, change division name to OVIK Health
3.1	G. Atwood	04-SEP-2024	Add Codes 7800TLC-02, 7800TLC-06 and 7802TN-16