

## EU Declaration of Conformity

Product Family: Two Layer Compression (TLC) Elastic  
Bandage, Non-Latex Family

### Manufacturer Details

<b>Legal Manufacturer</b>	Andover Healthcare Inc
<b>Manufacturer's Registered Address</b>	9 Fanaras Drive Salisbury, MA 01952 USA
<b>SRN</b>	US-MF-000035055

### EU Authorised Representative Details

<b>EU Authorised Representative:</b>	Advena Limited.
<b>Registered Address</b>	Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>SRN Number</b>	MT-AR-000000234

### Description of Conformity Procedure

**Class I:** Utilising Article 52(7) to self-certify the product after drawing up the Technical Documentation compliant to Annex II & III and Declaration of Conformity as per Annex IV of the European Medical Device Regulation EU MDR 2017/745.

### Statement of Conformity

Andover Healthcare Inc. hereby declares by this EU D.O.C that the Medical Device(s) or products listed in appendix 1 are in conformity with the European Union Medical Device Regulation (EU MDR) 2017/745 and associated Common Specifications or Harmonized Standards where applicable. The Medical Device(s) have been manufactured and controlled under the Quality Management System certified to ISO 13485.

We, Andover Healthcare Inc. declare that this EU D.O.C has been issued under our sole responsibility as the legal manufacturer of the specified products listed.

**Issued By** Sherry Albritton **Position** Director of Quality and Regulatory Affairs  
**Signed**  **Date** 03-OCT-2025 **Place of Issue** USA

## Applicable Standards and Certificates

Complying Standard	Description
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14971: 2019	Medical devices - Application of risk management to medical devices
ISO 10993-1: 2018	Biological evaluation of medical devices. Evaluation and testing within a risk management process
ISO 10993-5: 2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity
ISO 10993-10: 2013	Biological evaluation of medical devices. Tests for irritation and skin sensitization
ISO 15223-1: 2016	Medical devices - Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
EN ISO 20417:2021	Medical devices- Information to be supplied by the manufacturer

## Appendix 1: Medical Devices in Scope

<b>Medical Device Family Name</b>	Two Layer Compression (TLC) Elastic Bandage, Non-Latex Family
<b>Basic UDI-DI:</b>	0724004610675PG
<b>Risk Class &amp; Rule</b>	Class 1 (Rule 1)
<b>EMDN Code:</b>	M03040299
<b>Intended Purpose</b>	CoFlex/AndoFlex/Unna Boot Two Layer Compression (TLC) bandages are designed to help treat venous leg ulcers and other related conditions.

Trade name	Product Code	Description
TLC	7802TLC-TN	7802TLC-TN TLC LT.BL SS LT W/IN 4"
TLC	7902TLC-TN	7902TLC-TN TLC LT.BL LS LT W/IN 4"
TLC	7802TN-022	7802TN-22 TLC SS LT L2 W/IN 3"X3.8YD 32R
TLC	7802TN-26	7802TN-26 TLC SS LT L2 W/IN 6"X3.8YD 15R
TLC	7902TLC-TN-INTL	7902TLC-TN-INTL TLC LT.BL LS LT W/IN 4"
TLC	7802TLC-TN-INTL	7802TLC-TN-INTL TLC LT.BL SS LT W/IN 4"
TLC	7802TLC-06	7802TLC-06 TLC LT.BL SS LITE W/IN 6"
TLC	ASP-7805TLC-TN	ASP-7805TLC-TN TLC LT.BL STD W/IN 4"
TLC	ASP-7805TLC-XL	ASP-7805TLC-XL TLC LT.BL XL W/IN 4"
TLC	ASP-7905TLC-TN	ASP-7905TLC-TN TLC LT.BL LS STD W/IN 4"
TLC	ASP-7807TLC-TN	ASP-7807TLC-TN TLC LT.BL LT W/IN 4"
TLC	ASP-7907TLC-TN	ASP-7907TLC-TN TLC LT.BL LS LITE W/IN 4"
TLC	7802TN-14 TLC	7802TN-14 TLC LT.BL FOAM L1 4"X3YD 18R

Trade name	Product Code	Description
TLC	7800TLC-TN TLC	7800TLC-TN TLC LT.BL SS STD W/IN 4"
TLC	7800TLC-XL TLC	7800TLC-XL TLC LT.BL SS XL W/IN 4"
TLC	7900TLC-TN TLC	7900TLC-TN TLC LS STD W/IN 4"8K
TLC	7800TN-12	7800TN-12 TLC LT.BL FOAM L1 2"X1.3YD 32R
TLC	7800TN-13	7800TN-13 TLC LT.BL FOAM L1 3"X3YD 18R
TLC	7802TN-16	7802TN-16 TLC LT.BL FOAM L1 6"X3YD 10R
TLC	7800TLC-02	7800TLC-02 TLC LT.BL STD SS 2"
TLC	7800TN-22	7800TN-22 TLC SS STD L2 2"X3YD 32R
TLC	7800TN-14	7800TN-14 TLC LT.BL FOAM L1 4"X3.8YD 18R
TLC	7800TN-16	7800TN-16 TLC LT.BL FOAM L1 6"X3.8YD 10R
TLC	7800TN-24	7800TN-24 TLC SS STD L2 4"X5YD 32R
TLC	7800TN-26	7800TN-26 TLC SS STD L2 6"X5YD 15R
TLC	7800TLC-06	7800TLC-06 TLC LT.BL SS STD W/IN 6"
TLC	7802TN-24	7802TN-24 TLC SS LT L2 W/IN 4"X3.8YD 32R
TLC	7800TLC-TN-INTL	7800TLC-TN-INTL TLC LT.BL SS STD W/IN 4"
TLC	7800TLC-XL-INTL	7800TLC-XL-INTL TLC LT.BL SS XL W/IN 4"
TLC	7900TLC-TN-INTL	7900TLC-TN-INTL TLC LT.BL LS STD W/IN 4"
TLC	8830UBC-TN	8830UBC-TN UBC LT W/IN 3"
TLC	8840UBC-TN	8840UBC-TN UBC LT W/IN 4"
TLC	8830UBC-SC	8830UBC-SC UBC STD W/IN 3"
TLC	8840UBC-SC	8840UBC-SC UBC STD W/IN 4"
TLC	8830UBZ-SC	8830UBZ-SC UBZ STD W/IN 3"
TLC	8840UBZ-SC	8840UBZ-SC UBZ STD W/IN 4"
TLC	ASP-8830UBC-TN	ASP-8830UBC-TN UBC LT PF W/IN 3"
TLC	ASP-8840UBC-TN	ASP-8840UBC-TN UBC LT PF W/IN 4"
TLC	ASP-8830UBC-SC	ASP-8830UBC-SC UBC STD PF W/IN 3"
TLC	ASP-8840UBC-SC	ASP-8840UBC-SC UBC STD PF W/IN 4"
TLC	8840UBC-SC-APX	8840UBC-SC-APX UBC STD W/IN 4"
TLC	8830UBC-TN-APX	8830UBC-TN-APX UBC LT W/IN 3"
TLC	8830UBC-SC-APX	8830UBC-SC-APX UBC STD W/IN 3"
TLC	8840UBC-TN-APX	8840UBC-TN-APX UBC LT W/IN 4"
TLC	8840UBC-SC-INTL	8840UBC-SC-INTL UBC STD W/IN 4"
TLC	8830UBC-TN-INTL	8830UBC-TN-INTL UBC LT W/IN 3"
TLC	8830UBC-SC-INTL	8830UBC-SC-INTL UBC STD W/IN 3"
TLC	8840UBC-TN-INTL	8840UBC-TN-INTL UBC LT W/IN 4"
TLC	8830UBZ-TN	8830UBZ-TN UBZ LT W/IN 3"
TLC	8840UBZ-TN	8840UBZ-TN UBZ LT W/IN 4"
TLC	ASP-8830UBZ-TN	ASP-8830UBZ-TN UBZ LT PF W/IN 3"
TLC	ASP-8840UBZ-TN	ASP-8840UBZ-TN UBZ LT PF W/IN 4"
TLC	ASP-8840UBZ-SC	ASP-8840UBZ-SC UBZ STD PF W/IN 4"
TLC	8840UBZ-SC-APX	8840UBZ-SC-APX UBZ STD W/IN 4"
TLC	8830UBZ-SC-APX	8830UBZ-SC-APX UBZ STD W/IN 3"
TLC	8830UBZ-TN-APX	8830UBZ-TN-APX UBZ LT W/IN 3"

Trade name	Product Code	Description
TLC	8840UBZ-TN-APX	8840UBZ-TN-APX UBZ LT W/IN 4"
TLC	8840UBZ-TN-INTL	8840UBZ-TN-INTL UBZ LT W/IN 4"
TLC	8840UBZ-SC-INTL	8840UBZ-SC-INTL UBZ STD W/IN 4"
TLC	8830UBZ-TN-INTL	8830UBZ-TN-INTL UBZ LT W/IN 3"
TLC	8830UBZ-SC-INTL	8830UBZ-SC-INTL UBZ STD W/IN 3"
TLC	UB840C-01	UB840C-01 UBC SING 4"X6YD 12R
TLC	UB830C-01	UB830C-01 UBC SING 3"X6YD 12R
TLC	ASP-UB840C-01	ASP-UB840C-01 ANDFLX UBC SING 4"X6YD 12R
TLC	UB830Z-01	UB830Z-01 UBZ SING 3"X6YD 12R
TLC	UB840Z-01	UB840Z-01 UBZ SING 4"X6YD 12R
TLC	ASP-UB840Z-01	ASP-UB840Z-01 ANDFLX UBZ SING 4"X6YD 12R
TLC	7802TN-21	7802TN-21 TLC LITE LY2 1"X3.8YD 36
TLC	ASP-8830UBZ-SC	ASP-8830UBZ-SC ANDOFLEX ZINC STD 3"
TLC	ASP-UB830C-01	ASP-UB830C-01 ANDOFLX UBC SINGLE 3"
TLC	ASP-UB830Z-01	ASP-UB830Z-01 ANDOFLX UBZ SINGLE 3"

### 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
4.0	S. Albritton	12-MAY-2025	Updated the D.O.C format and variants listed
4.1	S. Albritton	12-OCT-2025	Addition of codes