

EU Declaration of Conformity

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

Manufacturer Details

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

EU Authorised Representative Details

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

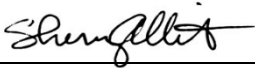
Description of Conformity Procedure

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	10-SEP-2026
		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

Medical Device Family Name	Two Layer Compression (TLC) Elastic Bandage, Non-Latex Family
Risk Class & Rule	Class 1 (Rule 1)
EMDN Code:	M03040299
Intended Purpose	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	BUDI-DI
AndoFlex TLC Calamine Lite	ASP-8830UBC-TN	ASP-8830UBC-TN UBC LT PF W/IN 3"	0724004AndFlxTLCCAL LiteX6
AndoFlex TLC Calamine Lite	ASP-8840UBC-TN	ASP-8840UBC-TN UBC LT PF W/IN 4"	
AndoFlex TLC Calamine Standard	ASP-8830UBC-SC	ASP-8830UBC-SC UBC STD PF W/IN 3"	0724004AndFlxTLCCAL STDW7
AndoFlex TLC Calamine Standard	ASP-8840UBC-SC	ASP-8840UBC-SC UBC STD PF W/IN 4"	
AndoFlex TLC LS Lite	ASP-7907TLC-TN	ASP-7907TLC-TN TLC LT.BL LS LITE W/IN 4"	0724004AndFlxTLCLSLiteF3
AndoFlex TLC Zinc Lite	ASP-8830UBZ-TN	ASP-8830UBZ-TN UBZ LT PF W/IN 3"	0724004AndFlxTLCZNLiteK2

Trade name	Product Code	Description	BUDI-DI
AndoFlex TLC Zinc Lite	ASP-8840UBZ-TN	ASP-8840UBZ-TN UBZ LT PF W/IN 4"	
AndoFlex TLC Zinc Standard	ASP-8840UBZ-SC	ASP-8840UBZ-SC UBZ STD PF W/IN 4"	0724004AndFlxTLCZNS TDN7
AndoFlex TLC Zinc Standard	ASP-8830UBZ-SC	ASP-8830UBZ-SC ANDOFLEX ZINC STD 3"	
AndoFlex Zinc Single	ASP-UB840Z-01	ASP-UB840Z-01 ANDFLX UBZ SING 4"X6YD 12R	0724004AndFlxZNSNG LMY
AndoFlex Zinc Single	ASP-UB830Z-01	ASP-UB830Z-01 ANDOFLX UBZ SINGLE 3"	
AndoFlex Calamine Single	ASP-UB840C-01	ASP-UB840C-01 ANDFLX UBC SING 4"X6YD 12R	0724004AndoFlexCALSNGLXU
AndoFlex Calamine Single	ASP-UB830C-01	ASP-UB830C-01 ANDOFLX UBC SINGLE 3"	
AndoFlex TLC Lite	ASP-7807TLC-TN	ASP-7807TLC-TN TLC LT.BL LT W/IN 4"	0724004AndoFlexTLC LiteH9
AndoFlex TLC LS	ASP-7905TLC-TN	ASP-7905TLC-TN TLC LT.BL LS STD W/IN 4"	0724004AndoFlexTLC LSQC
AndoFlex TLC	ASP-7805TLC-TN	ASP-7805TLC-TN TLC LT.BL STD W/IN 4"	0724004AndoFlexTLC PG
AndoFlex TLC XL	ASP-7805TLC-XL	ASP-7805TLC-XL TLC LT.BL XL W/IN 4"	0724004AndoFlexTLCX LR2
CoFlex TLC	7800TLC-TN TLC	7800TLC-TN TLC LT.BL SS STD W/IN 4"	0724004CoFlexTLCAY
CoFlex TLC	7800TLC-02	7800TLC-02 TLC LT.BL STD SS 2"	
CoFlex TLC	7800TLC-06	7800TLC-06 TLC LT.BL SS STD W/IN 6"	
CoFlex TLC	7800TLC-TN-INTL	7800TLC-TN-INTL TLC LT.BL SS STD W/IN 4"	
CoFlex TLC Calamine	8830UBC-TN	8830UBC-TN UBC LT W/IN 3"	0724004CoFlexTLC CalaminUJ
CoFlex TLC Calamine	8840UBC-TN	8840UBC-TN UBC LT W/IN 4"	
CoFlex TLC Calamine	8830UBC-TN-APX	8830UBC-TN-APX UBC LT W/IN 3"	
CoFlex TLC Calamine	8840UBC-TN-APX	8840UBC-TN-APX UBC LT W/IN 4"	
CoFlex TLC Calamine	8830UBC-TN-INTL	8830UBC-TN-INTL UBC LT W/IN 3"	
CoFlex TLC Calamine	8840UBC-TN-INTL	8840UBC-TN-INTL UBC LT W/IN 4"	
CoFlex TLC Calamine Standard	8830UBC-SC	8830UBC-SC UBC STD W/IN 3"	0724004COFLEXTLCC ALSTDBE

Trade name	Product Code	Description	BUDI-DI
CoFlex TLC Calamine Standard	8840UBC-SC	8840UBC-SC UBC STD W/IN 4"	
CoFlex TLC Calamine Standard	8840UBC-SC-APX	8840UBC-SC-APX UBC STD W/IN 4"	
CoFlex TLC Calamine Standard	8830UBC-SC-APX	8830UBC-SC-APX UBC STD W/IN 3"	
CoFlex TLC Calamine Standard	8840UBC-SC-INTL	8840UBC-SC-INTL UBC STD W/IN 4"	
CoFlex TLC Calamine Standard	8830UBC-SC-INTL	8830UBC-SC-INTL UBC STD W/IN 3"	
COFLEX TLC LITE	7802TLC-TN	7802TLC-TN TLC LT.BL SS LT W/IN 4"	0724004CoFlexTLCCLITE XL
COFLEX TLC LITE	7902TLC-TN	7902TLC-TN TLC LT.BL LS LT W/IN 4"	
COFLEX TLC LITE	7802TN-022	7802TN-22 TLC SS LT L2 W/IN 3"X3.8YD 32R	
COFLEX TLC LITE	7802TN-26	7802TN-26 TLC SS LT L2 W/IN 6"X3.8YD 15R	
COFLEX TLC LITE	7902TLC-TN-INTL	7902TLC-TN-INTL TLC LT.BL LS LT W/IN 4"	
COFLEX TLC LITE	7802TLC-TN-INTL	7802TLC-TN-INTL TLC LT.BL SS LT W/IN 4"	
COFLEX TLC LITE	7802TLC-06	7802TLC-06 TLC LT.BL SS LITE W/IN 6"	
CoFlex TLC LS	7900TLC-TN TLC	7900TLC-TN TLC LS STD W/IN 4"8K	0724004CoFlexTLCCLSA X
CoFlex TLC LS	7900TLC-TN-INTL	7900TLC-TN-INTL TLC LT.BL LS STD W/IN 4"	
CoFlex TLC Single	7802TN-14 TLC	7802TN-14 TLC LT.BL FOAM L1 4"X3YD 18R	0724004CoFlexTLCSingleYN
CoFlex TLC Single	7800TN-12	7800TN-12 TLC LT.BL FOAM L1 2"X1.3YD 32R	
CoFlex TLC Single	7800TN-13	7800TN-13 TLC LT.BL FOAM L1 3"X3YD 18R	
CoFlex TLC Single	7802TN-16	7802TN-16 TLC LT.BL FOAM L1 6"X3YD 10R	
CoFlex TLC Single	7800TN-22	7800TN-22 TLC SS STD L2 2"X3YD 32R	
CoFlex TLC Single	7800TN-14	7800TN-14 TLC LT.BL FOAM L1 4"X3.8YD 18R	
CoFlex TLC Single	7800TN-16	7800TN-16 TLC LT.BL FOAM L1 6"X3.8YD 10R	
CoFlex TLC Single	7800TN-24	7800TN-24 TLC SS STD L2 4"X5YD 32R	
CoFlex TLC Single	7800TN-26	7800TN-26 TLC SS STD L2 6"X5YD 15R	

Trade name	Product Code	Description	BUDI-DI
CoFlex TLC Single	7802TN-24	7802TN-24 TLC SS LT L2 W/IN 4"X3.8YD 32R	
CoFlex TLC Single	7802TN-21	7802TN-21 TLC LITE LY2 1"X3.8YD 36	
CoFlex TLC Single Calamine	UB840C-01	UB840C-01 UBC SING 4"X6YD 12R	0724004COFLEXTLCS NGLCALZV
CoFlex TLC Single Calamine	UB830C-01	UB830C-01 UBC SING 3"X6YD 12R	
CoFlex TLC Single Zinc	UB830Z-01	UB830Z-01 UBZ SING 3"X6YD 12R	0724004COFLEXTLCS NGLZNMD
CoFlex TLC Single Zinc	UB840Z-01	UB840Z-01 UBZ SING 4"X6YD 12R	
CoFlex TLC XL	7800TLC-XL TLC	7800TLC-XL TLC LT.BL SS XL W/IN 4"	0724004CoFlexTLCXLB M
CoFlex TLC XL	7800TLC-XL-INTL	7800TLC-XL-INTL TLC LT.BL SS XL W/IN 4"	
CoFlex TLC Zinc	8830UBZ-TN	8830UBZ-TN UBZ LT W/IN 3"	0724004CoFlexTLCZin cAH
CoFlex TLC Zinc	8840UBZ-TN	8840UBZ-TN UBZ LT W/IN 4"	
CoFlex TLC Zinc	8830UBZ-TN-APX	8830UBZ-TN-APX UBZ LT W/IN 3"	
CoFlex TLC Zinc	8840UBZ-TN-APX	8840UBZ-TN-APX UBZ LT W/IN 4"	
CoFlex TLC Zinc	8840UBZ-TN-INTL	8840UBZ-TN-INTL UBZ LT W/IN 4"	
CoFlex TLC Zinc	8830UBZ-TN-INTL	8830UBZ-TN-INTL UBZ LT W/IN 3"	
CoFlex TLC Zinc Standard	8830UBZ-SC	8830UBZ-SC UBZ STD W/IN 3"	0724004COFLEXTLCZN STDDY
CoFlex TLC Zinc Standard	8840UBZ-SC	8840UBZ-SC UBZ STD W/IN 4"	
CoFlex TLC Zinc Standard	8840UBZ-SC-APX	8840UBZ-SC-APX UBZ STD W/IN 4"	
CoFlex TLC Zinc Standard	8830UBZ-SC-APX	8830UBZ-SC-APX UBZ STD W/IN 3"	
CoFlex TLC Zinc Standard	8840UBZ-SC-INTL	8840UBZ-SC-INTL UBZ STD W/IN 4"	
CoFlex TLC Zinc Standard	8830UBZ-SC-INTL	8830UBZ-SC-INTL UBZ STD W/IN 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
5.0	S. Albritton	10 SEP 2026	Addition of new BUDI-DI codes as used in EUDAMED