

Declaration of Conformity


for the Cohesive Elastic Bandages Family

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices.

The undersigned declares 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:	Cohesive Elastic Bandages
Legal Manufacturer: (Name on Label)	Andover Healthcare, Inc (a subsidiary of OVIK Health LLC.) 9 Fanaras Drive Salisbury, MA 01952 USA
Manufacturers SRN:	US-MF-000035055
Basic UDI-DI:	0724004724004PF
Variants:	See Appendix II (this document) – Product Listing/Schedule
Intended Purpose:	CoFlex cohesive bandage is intended for use as an elastic wrap to compress, support, or secure primary dressings or devices.
MDR Classification:	Class I [Rule 1]
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Floor, 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 EU MDR 2017/745.

Name Genoa Atwood Position Regulatory Affairs Manager

Signed  Date 05/OCT/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	Description/Document Name
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 Number	Device Name (R/C=Rolls per Case)	GMDN	EMDN
3100CP-030	CoFlex Color Pack 1"X5YD 30R/C	59015	M030402020101
3100TN-030	COFLEX Tan 1"X5YD 30R/C	59015	M030402020101
3200CP-036	CoFlex Color Pack 2"X5YD 36R/C	59015	M030402020101
3200TN-036	CoFlex Tan 2"X5YD 36R/C	59015	M030402020101
3300BL-024	CoFlex Blue 3"X5YD 24R/C	59015	M030402020101
3300CP-024	CoFlex Color Pack 3"X5YD 24R/C	59015	M030402020101
3300TN-024	CoFlex Tan 3"X5YD 24R/C	59015	M030402020101
3400BL-018	COFLEX Blue 4"X5YD 18R/C	59015	M030402020101
3400CP-018	CoFlex Color Pack 4"X5YD 18R/C	59015	M030402020101
3400L-018	CoFlex Tan 4"X6.5YD 18R/C	59015	M030402020101
3400TN-018	CoFlex Tan 4"X5YD 18R/C	59015	M030402020101
3720WH-24	PowerFlex White 2"X6YD 24R/C	59015	M030402020101
3730WH-16	PowerFlex White 3"X6YD 16R/C	59015	M030402020101
3740WH-12	PowerFlex White 4"X6YD 12R/C	59015	M030402020101
3815GR-048	PowerFlex Green 1.5"X6YD 48R/C	59015	M030402020101
3815LB-048	PowerFlex Lite Blue 1.5"X6YD 48R/C	59015	M030402020101
3815NG-048	PowerFlex Neon Green 1.5"X6YD 48R/C	59015	M030402020101
3815NP-048	PowerFlex Neon Pink 1.5"X6YD 48R/CC	59015	M030402020101
3815OR-048	PowerFlex Orange 1.5"X6YD 48R/C	59015	M030402020101
3815PU-048	PowerFlex Purple 1.5"X6YD 48R/C	59015	M030402020101
3815YL-048	PowerFlex Yellow 1.5"X6YD 48R/C	59015	M030402020101
5100CP-030	CoFlex Non-Latex Color Pack 1"X5YD 30R/C	10284	M030402020101
5100GR-030	COFLEX NL Green 1"X5YD 30R/C	10284	M030402020101
5100NP-030	COFLEX NL Neon Pink 1"X5YD 30R/C	10284	M030402020101
5100TN-030	CoFlex Non-Latex Tan 1"X5YD 30R/C	10284	M030402020101
5100WH-030	COFLEX NL White 1"X5YD 30R/C	10284	M030402020101
5200CP-036	CoFlex Non-Latex Color Pack 2"X5YD 36R/C	10284	M030402020101
5200GR-036	COFLEX NL Green 2"X5YD 36R/C	10284	M030402020101

Catalogue Number	Device Name (R/C=Rolls per Case)	GMDN	EMDN
5200KP-036	CoFlex Non-Latex Kids Pack 2"X5YD 36R/C	10284	M030402020101
5200NP-036	COFLEX NL Neon Pink 2"X5YD 36R/C	10284	M030402020101
5200SC-036	COFLEX NL Smiley Pack 2"X5YD 36R/C	10284	M030402020101
5200TN-036	CoFlex Non-Latex Tan 2"X5YD 36R/C	10284	M030402020101
5200WH-036	COFLEX NL White 2"X5YD 36R/C	10284	M030402020101
5300BL-024	CoFlex Non-Latex Blue 3"X5YD 24R/C	10284	M030402020101
5300CP-024	CoFlex Non-Latex Color Pack 3"X5YD 24R/C	10284	M030402020101
5300GR-024	COFLEX NL Green 3"X5YD 24R/C	10284	M030402020101
5300KP-024	CoFlex Non-Latex Kids Pack 3"X5YD 24 R/C	10284	M030402020101
5300NP-024	COFLEX NL Neon Pink 3"X5YD 24R/C	10284	M030402020101
5300TN-024	CoFlex Non-Latex Tan 3"X5YD 24R/C	10284	M030402020101
5300WH-024	COFLEX NL White 3"X5YD 24R/C	10284	M030402020101
5400BL-018	CoFlex Non-Latex Blue 4"X5YD 18R/C	10284	M030402020101
5400CP-018	CoFlex Non-Latex Color Pack 4"X5YD 18R/C	10284	M030402020101
5400GR-018	COFLEX NL Green 4"X5YD 18R/C	10284	M030402020101
5400NP-018	COFLEX NL Neon Pink 4"X5YD 18R/C	10284	M030402020101
5400TN-018	CoFlex Non-Latex Tan 4"X5YD 18R/C	10284	M030402020101
5400WH-018	COFLEX NL White 4"X5YD 18R/C	10284	M030402020101
9100CP-030	CoFlex Latex Free 2 Color Pack 1"X5YD 30R/C	10284	M030402020101
9150CP-048	CoFlex LF2 Color Pack 1.5"X5YD 48 R/C	10284	M030402020101
9200CP-036	CoFlex LF2 Color Pack 1"X5YD 30 R/C	10284	M030402020101
9300CP-024	CoFlex LF2 Color Pack 3"X5YD 24 R/C	10284	M030402020101
9300TN-024	CoFlex LF2 Tan 3"X5YD 24 R/C	10284	M030402020101
9400CP-018	CoFlex LF2 Color Pack 4"X5YD 18 R/C	10284	M030402020101
9400TN-018	CoFlex Latex Free 2 Tan 4"X5YD 18R/C	10284	M030402020101
9430UM-100	Universal Medic Absorbent Foam Dressing Black 4"X3.7YD 100 R/C	10284	M030402020101
9430UM-18	Universal Medic Absorbent Foam Dressing Black 4"X3.7YD 18R/C	10284	M030402020101
ASP-5400TN-018	ASP-5400TN-018 ANDOFLEX NL TN 4"X5Y	10284	M030402020101
ASP-5400TN-018	ASP-5400L-018 ANDOFLEX NL TN 4"X6.5	10284	M030402020101

Version History

Version	Compiled by	Date	Description
1.0	G. Atwood	23JUN2022	New Document
2.0	G. Atwood	16MAR2023	Added product codes: vbg.
2.1	G. Atwood	28SEP2023	Addition of SRN number
3.0	G. Atwood	27MAR2024	Addition of product codes: PowerFlex, Change division name to OVIK Health
3.1	G. Atwood	01JUL2024	Addition of ASP codes
3.2	G. Atwood	08JUL2024	Addition of 9100 – 9400 codes
3.3	G. Atwood	14AUG2024	Update Appendix II with current International EU Catalogue #'s
3.4	G. Atwood	05/OCT/2024	Add 3720WH-24, 3730WH-16 and 3740WH-12