

EU Declaration of Conformity

Product Family: Cohesive Elastic Bandages

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** 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

Medical Device Family Name	Cohesive Elastic Bandages
Basic UDI-DI:	0724004724004PF
Risk Class & Rule	Class 1 (Rule 1)
EMDN Code:	M030402020101
Intended Purpose	CoFlex cohesive bandage is intended for use as an elastic wrap to compress, support, or secure primary dressings or devices.

Trade name	Product Code	Description
COFLEX	3200BL-036	3200BL CFX LATEX BLUE 2"X5YD 36R
COFLEX	3300BL-024	3300BL CFX LATEX BLUE 3"X5YD 24R
COFLEX	3100CP-030	3100CP CFX LATEX CP 1"X5YD 30R
COFLEX	3200CP-036	3200CP CFX LATEX CP 2"X5YD 36R
COFLEX	3300CP-024	3300CP CFX LATEX CP 3"X5YD 24R
COFLEX	3400CP-018	3400CP CFX LATEX CP 4"X5YD 18R
COFLEX	3300RB-024	3300RB CFX LATEX RAINBOW 3"X5YD 24R
COFLEX	3100TN-030	3100TN CFX LATEX TAN 1"X5YD 30R
COFLEX	3150TN-048	3150TN CFX LATEX TAN 1.5"X5YD 48R
COFLEX	3200TN-036	3200TN CFX LATEX TAN 2"X5YD 36R
COFLEX	3300TN-024	3300TN CFX LATEX TAN 3"X5YD 24R
COFLEX	3400TN-018	3400TN CFX LATEX TAN 4"X5YD 18R
COFLEX	3400L-018	3400L CFX LATEX TAN 4"X6.5YD 18R
COFLEX	3100BL-030	3100BL CFX LATEX BLUE 1"X5YD 30R

Trade name	Product Code	Description
COFLEX	3150BL-048	3150BL CFX LATEX BLUE 1.5"X5YD 48R
COFLEX	3400BL-018	3400BL CFX LATEX BLUE 4"X5YD 18R
COFLEX	3150CP-048	3150CP CFX LATEX CP 1.5"X5YD 48R
COFLEX	3100RB-030	3100RB CFX LATEX RAINBOW 1"X5YD 30R
COFLEX	3150RB-048	3150RB CFX LATEX RAINBOW 1.5"X5YD 48R
COFLEX	3200RB-036	3200RB CFX LATEX RAINBOW 2"X5YD 36R
COFLEX	3600TN-012	3600TN CFX LATEX TAN 6"X5YD 12R
COFLEX	3300BL-024	3300BL-INTL CFX LATEX BLUE 3"X5YD 24R
COFLEX	3100CP-030	3100CP-INTL CFX LATEX CP 1"X5YD 30R
COFLEX	3400CP-018	3400CP-INTL CFX LATEX CP 4"X5YD 18R
COFLEX	3300TN-024	3300TN-INTL CFX LATEX TAN 3"X5YD 24R
COFLEX	3400TN-018	3400TN-INTL CFX LATEX TAN 4"X5YD 18R
COFLEX	3400L-018	3400L-INTL CFX LATEX TAN 4"X6.5YD 18R
COFLEX	3300CP-024	3300CP-INTL CFX LATEX CP 3"X5YD 24R
COFLEX	3200TN-036	3200TN-INTL CFX LATEX TAN 2"X5YD 36R
COFLEX	3100TN-030	3100TN-INTL CFX LATEX TAN 1"X5YD 30R
COFLEX	3400BL-018	3400BL-INTL CFX LATEX BLUE 4"X5YD 18R
COFLEX	3100BL-030	3100BL-INTL CFX LATEX BLUE 1"X5YD 30R
COFLEX	3150BL-048	3150BL-INTL CFX LATEX BLUE 1.5"X5YD 48R
COFLEX	3150TN-048	3150TN-INTL CFX LATEX TAN 1.5"X5YD 48R
COFLEX	3200BL-036	3200BL-INTL CFX LATEX BLUE 2"X5YD 36R
COFLEX	3200CP-036	3200CP-INTL CFX LATEX CP 2"X5YD 36R
COFLEX	9740TN-08	9740TN CFX AFD TAN 4"X2.5YD 8R
COFLEX	9720TN-016	9720TN CFX AFD TAN 2"X2.5YD 16R
COFLEX	9100CP-030	9100CP CFX LF2 CP 1"X5YD 30R
COFLEX	9200CP-036	9200CP CFX LF2 CP 2"X5YD 36R
COFLEX	9300CP-024	9300CP CFX LF2 CP 3"X5YD 24R
COFLEX	9400CP-018	9400CP CFX LF2 CP 4"X5YD 18R
COFLEX	9100TN-030	9100TN CFX LF2 TAN 1"X5YD 30R
COFLEX	9150TN-048	9150TN CFX LF2 TAN 1.5"X5YD 48R
COFLEX	9200TN-036	9200TN CFX LF2 TAN 2"X5YD 36R
COFLEX	9300TN-024	9300TN CFX LF2 TAN 3"X5YD 24R
COFLEX	9400TN-018	9400TN CFX LF2 TAN 4"X5YD 18R
COFLEX	9600TN-012	9600TN CFX LF2 TAN 6"X5YD 12R
COFLEX	9150CP-048	9150CP CFX LF2 CP 1.5"X5YD 48R
COFLEX	9200TN-0168	9200TN-168 CFX LF2 TAN 2"X5YD 168R
COFLEX	9202TN-0168	9202TN-168 CFX LF2 TAN 2"X5YD 168R
COFLEX	9303TN-0112	9303TN-112 CFX LF2 TAN 3"X5YD 112R
COFLEX	9404TN-084	9404TN-084 CFX LF2 TAN 4"X5YD 84R
COFLEX	9606TN-056	9606TN-056 CFX LF2 TAN 6"X5YD 56R
COFLEX	9400TN-018	9400TN-INTL CFX LF2 TAN 4"X5YD 18R
COFLEX	9200CP-036	9200CP-INTL CFX LF2 CP 2"X5YD 36R
COFLEX	9300CP-024	9300CP-INTL CFX LF2 CP 3"X5YD 24R

Trade name	Product Code	Description
COFLEX	7600TN-012	7600TN CFX MED TAN 6"X5YD 12R
COFLEX	7100CP-030	7100CP CFX MED CP 1"X5YD 30R
COFLEX	7150CP-048	7150CP CFX MED CP 1.5"X5YD 48R
COFLEX	7200CP-036	7200CP CFX MED CP 2"X5YD 36R
COFLEX	7300CP-024	7300CP CFX MED CP 3"X5YD 24R
COFLEX	7400CP-018	7400CP CFX MED CP 4"X5YD 18R
COFLEX	7100TN-030	7100TN CFX MED TAN 1"X5YD 30R
COFLEX	7150TN-048	7150TN CFX MED TAN 1.5"X5YD 48R
COFLEX	7200TN-036	7200TN CFX MED TAN 2"X5YD 36R
COFLEX	7200TN-0240	7200TN-240 CFX MED TAN 2"X5YD 240R
COFLEX	7300TN-024	7300TN CFX MED TAN 3"X5YD 24R
COFLEX	7400TN-018	7400TN CFX MED TAN 4"X5YD 18R
COFLEX	7400TN-0120	7400TN-120 CFX MED TAN 4"X5YD 120R
COFLEX	7600TN-080	7600TN-080 CFX MED TAN 6"X5YD 80R
COFLEX	5300BK-024	5300BK CFX NL BLACK 3"X5YD 24R
COFLEX	5200BL-036	5200BL CFX NL BLUE 2"X5YD 36R
COFLEX	5300BL-024	5300BL CFX NL BLUE 3"X5YD 24R
COFLEX	5100CP-030	5100CP CFX NL CP 1"X5YD 30R
COFLEX	5150CP-048	5150CP CFX NL CP 1.5"X5YD 48R
COFLEX	5200CP-036	5200CP CFX NL CP 2"X5YD 36R
COFLEX	5300CP-024	5300CP CFX NL CP 3"X5YD 24R
COFLEX	5400CP-018	5400CP CFX NL CP 4"X5YD 18R
COFLEX	5200KP-036	5200KP CFX NL KP 2"X5YD 36R
COFLEX	5300KP-024	5300KP CFX NL KP 3"X5YD 24R
COFLEX	5400KP-018	5400KP CFX NL KP 4"X5YD 18R
COFLEX	5200NG-036	5200NG CFX NL N.GRN 2"X5YD 36R
COFLEX	5200RB-036	5200RB CFX NL RAINBOW 2"X5YD 36R
COFLEX	5300RB-024	5300RB CFX NL RAINBOW 3"X5YD 24R
COFLEX	5300RD-024	5300RD CFX NL RED 3"X5YD 24R
COFLEX	5200SC-036	5200SC CFX NL SM PACK 2"X5YD 36R
COFLEX	5300SC-024	5300SC CFX NL SM PACK 3"X5YD 24R
COFLEX	5100TN-030	5100TN CFX NL TAN 1"X5YD 30R
COFLEX	5200TN-036	5200TN CFX NL TAN 2"X5YD 36R
COFLEX	5300TN-024	5300TN CFX NL TAN 3"X5YD 24R
COFLEX	5400TN-018	5400TN CFX NL TAN 4"X5YD 18R
COFLEX	5100LC-072	5100LC-072 LAB CORP CFX NL CP 1"X5YD 72R
COFLEX	5200LC-072	5200LC-072 LAB CORP CFX NL CP 2"X5YD 72R
COFLEX	5100BL-030	5100BL CFX NL BLUE 1"X5YD 30R
COFLEX	5150BL-048	5150BL CFX NL BLUE 1.5"X5YD 48R
COFLEX	5400BL-018	5400BL CFX NL BLUE 4"X5YD 18R
COFLEX	5400LB-084	5400LB-084 CFX NL LT.BLUE 4"X5YD 84R
COFLEX	5100RB-030	5100RB CFX NL RAINBOW 1"X5YD 30R
COFLEX	5150RB-048	5150RB CFX NL RAINBOW 1.5"X5YD 48R

Trade name	Product Code	Description
COFLEX	5150RD-048	5150RD CFX NL RED 1.5"X5YD 48R
COFLEX	5150TN-048	5150TN CFX NL TAN 1.5"X5YD 48R
COFLEX	5300PTN-0112	5300PTN-112 CFX NL TAN 3"X5YD 112R
COFLEX	5400TN-0100	5400TN-100 CFX NL TAN 4"X5YD 100R
COFLEX	5600TN-012	5600TN CFX NL TAN 6"X5YD 12R
COFLEX	5600TN-072	5600TN-072 CFX NL TAN 6"X5YD 72R
COFLEX	5300WH-024	5300WH CFX NL WHT 3"X5YD 24R
COFLEX	5900CP-0125	5900CP CFX NL BB CP 1.25"X6YD 125R
COFLEX	5910CP-075	5910CP CFX NL BB CP 2"X6YD 75R
COFLEX	5400L-018	5400L CFX NL TAN 4"X6.5YD 18R
COFLEX	5600L-012	5600L CFX NL TAN 6"X6.5YD 12R
COFLEX	5300PF-0112	5300PF-112 CFX NL TAN 3"X5YD 112R
COFLEX	5300CP-024	5300CP-INTL CFX NL CP 3"X5YD 24R
COFLEX	5200KP-036	5200KP-INTL CFX NL KP 2"X5YD 36R
COFLEX	5300KP-024	5300KP-INTL CFX NL KP 3"X5YD 24R
COFLEX	5300BL-024	5300BL-INTL CFX NL BLUE 3"X5YD 24R
COFLEX	5100CP-030	5100CP-INTL CFX NL CP 1"X5YD 30R
COFLEX	5200CP-036	5200CP-INTL CFX NL CP 2"X5YD 36R
COFLEX	5300RD-024	5300RD-INTL CFX NL RED 3"X5YD 24R
COFLEX	5200SC-036	5200SC-INTL CFX NL SM PACK 2"X5YD 36R
COFLEX	5300SC-024	5300SC-INTL CFX NL SM PACK 3"X5YD 24R
COFLEX	5100TN-030	5100TN-INTL CFX NL TAN 1"X5YD 30R
COFLEX	5200TN-036	5200TN-INTL CFX NL TAN 2"X5YD 36R
COFLEX	5300TN-024	5300TN-INTL CFX NL TAN 3"X5YD 24R
COFLEX	5400TN-018	5400TN-INTL CFX NL TAN 4"X5YD 18R
COFLEX	5300BK-024	5300BK-INTL CFX NL BLACK 3"X5YD 24R
COFLEX	5300WH-024	5300WH-INTL CFX NL WHT 3"X5YD 24R
COFLEX	5200BL-036	5200BL-INTL CFX NL BLUE 2"X5YD 36R
COFLEX	5150BL-048	5150BL-INTL CFX NL BLUE 1.5"X5YD 48R
COFLEX	5150TN-048	5150TN-INTL CFX NL TAN 1.5"X5YD 48R
COFLEX	5400KP-018	5400KP-INTL CFX NL KP 4"X5YD 18R
COFLEX	5600KP-012	5600KP-INTL CFX NL KP 6"X5YD 12R
COFLEX	5150SC-048	5150SC-INTL CFX NL SM PACK 1.5"X5YD 48R
COFLEX	5400CP-018	5400CP-INTL CFX NL CP 4"X5YD 18R
COFLEX	5100WH-030	5100WH-INTL CFX NL WHT 1"X5YD 30R
COFLEX	5100GR-030	5100GR-INTL CFX NL GREEN 1"X5YD 30R
COFLEX	5200NP-036	5200NP-INTL CFX NL N.PINK 2"X5YD 36R
COFLEX	5300NP-024	5300NP-INTL CFX NL N.PINK 3"X5YD 24R
COFLEX	5200GR-036	5200GR-INTL CFX NL GREEN 2"X5YD 36R
COFLEX	5100NP-030	5100NP-INTL CFX NL N.PINK 1"X5YD 30R
COFLEX	5200WH-036	5200WH-INTL CFX NL WHT 2"X5YD 36R
COFLEX	5300GR-024	5300GR-INTL CFX NL GREEN 3"X5YD 24R
COFLEX	5400WH-018	5400WH-INTL CFX NL WHT 4"X5YD 18R

Trade name	Product Code	Description
COFLEX	5400GR-018	5400GR-INTL CFX NL GREEN 4"X5YD 18R
COFLEX	5400NP-018	5400NP-INTL CFX NL N.PINK 4"X5YD 18R
COFLEX	3815BK-048	3815BK PFX BLACK 1.5"X5YD 48R
COFLEX	3815BL-048	3815BL PFX BLUE 1.5"X5YD 48R
COFLEX	3820GR-0200	3820GR PFX GREEN 2"X5YD 200R
COFLEX	3815HP-048	3815HP PFX HOCKEY PK 1.5"X5YD 48R
COFLEX	3815RD-048	3815RD PFX RED 1.5"X5YD 48R
COFLEX	3815WH-048	3815WH PFX WHT 1.5"X5YD 48R
COFLEX	3815GR-048	3815GR PFX GREEN 1.5"X5YD 48R
COFLEX	3815YL-048	3815YL PFX YELLOW 1.5"X5YD 48R
COFLEX	3815NP-048	3815NP PFX N.PINK 1.5"X5YD 48R
COFLEX	3815NG-048	3815NG PFX N.GRN 1.5"X5YD 48R
COFLEX	3815PU-048	3815PU PFX PURPLE 1.5"X5YD 48R
COFLEX	3815OR-048	3815OR PFX ORANGE 1.5"X5YD 48R
COFLEX	3815LB-048	3815LB PFX LT.BLUE 1.5"X5YD 48R
COFLEX	3710BK-048	3710BK PFX BLACK 1"X6YD 48R
COFLEX	3715BK-032	3715BK PFX BLACK 1.5"X6YD 32R
COFLEX	3720BK-024	3720BK PFX BLACK 2"X6YD 24R
COFLEX	3725BK-016	3725BK PFX BLCK 2.75"X6YD 16R
COFLEX	4725BK-048	4725BK PFX BLACK PWRPK 2.75"X6YD 48R
COFLEX	3730BK-016	3730BK PFX BLACK 3"X6YD 16R
COFLEX	4730BK-048	4730BK PFX BLACK PWRPK 3"X6YD 48R
COFLEX	3740BK-012	3740BK PFX BLACK 4"X6YD 12R
COFLEX	3760BK-08	3760BK PFX BLACK 6"X6YD 8R
COFLEX	3715BL-032	3715BL PFX BLUE 1.5"X6YD 32R
COFLEX	3720BL-024	3720BL PFX BLUE 2"X6YD 24R
COFLEX	3730BL-016	3730BL PFX BLUE 3"X6YD 16R
COFLEX	3720GR-024	3720GR PFX GREEN 2"X6YD 24R
COFLEX	3730GR-016	3730GR PFX GREEN 3"X6YD 16R
COFLEX	3720GY-024	3720GY PFX GREY 2"X6YD 24R
COFLEX	3730GY-016	3730GY PFX GREY 3"X6YD 16R
COFLEX	3720LB-024	3720LB PFX LT.BLUE 2"X6YD 24R
COFLEX	3720MR-024	3720MR PFX MAROON 2"X6YD 24R
COFLEX	3730MR-016	3730MR PFX MAROON 3"X6YD 16R
COFLEX	3720NP-024	3720NP PFX N.PINK 2"X6YD 24R
COFLEX	3710NV-048	3710NV PFX NAVY 1"X6YD 48R
COFLEX	3715NV-032	3715NV PFX NAVY 1.5"X6YD 32R
COFLEX	3720NV-024	3720NV PFX NAVY 2"X6YD 24R
COFLEX	3725NV-016	3725NV PFX NAVY 2.75"X6YD 16R
COFLEX	3730NV-016	3730NV PFX NAVY 3"X6YD 16R
COFLEX	3720OR-024	3720OR PFX ORANGE 2"X6YD 24R
COFLEX	3730OR-016	3730OR PFX ORANGE 3"X6YD 16R
COFLEX	3720PU-024	3720PU PFX PURPLE 2"X6YD 24R

Trade name	Product Code	Description
COFLEX	3730PU-016	3730PU PFX PURPLE 3"X6YD 16R
COFLEX	3715RD-032	3715RD PFX RED 1.5"X6YD 32R
COFLEX	3720RD-024	3720RD PFX RED 2"X6YD 24R
COFLEX	3730RD-016	3730RD PFX RED 3"X6YD 16R
COFLEX	3720TN-024	3720TN PFX TAN 2"X6YD 24R
COFLEX	3710WH-048	3710WH PFX WHT 1"X6YD 48R
COFLEX	3715WH-032	3715WH PFX WHT 1.5"X6YD 32R
COFLEX	3720WH-024	3720WH PFX WHT 2"X6YD 24R
COFLEX	3725WH-016	3725WH PFX WHT 2.75"X6YD 16R
COFLEX	4725WH-048	4725WH PFX WHT PWRPK 2.75"X6YD 48R
COFLEX	3730WH-016	3730WH PFX WHT 3"X6YD 16R
COFLEX	4730WH-048	4730WH PFX WHT PWRPK 3"X6YD 48R
COFLEX	3740WH-012	3740WH PFX WHT 4"X6YD 12R
COFLEX	3760WH-08	3760WH PFX WHT 6"X6YD 8R
COFLEX	3720YL-024	3720YL PFX YELLOW 2"X6YD 24R
COFLEX	3722BK-016	3722BK PFX AFD BLACK 2"X2.5YD 16R
COFLEX	3744BK-08	3744BK PFX AFD BLACK 4"X2.5YD 8R
COFLEX	3722WH-016	3722WH PFX AFD WHT 2"X2.5YD 16R
COFLEX	3744WH-08	3744WH PFX AFD WHT 4"X2.5YD 8R
COFLEX	4815WH-032	4815WH PFX LF WHT 1.5"X6YD 32R
COFLEX	4820WH-024	4820WH PFX LF WHT 2"X6YD 24R
COFLEX	4830WH-016	4830WH PFX LF WHT 3"X6YD 16R
COFLEX	9430UM-01	9430UM-01 UMAFD BLACK 4"X3.7YD 1R
COFLEX	9430UM-018	9430UM UMAFD BLACK 4"X3.7YD 18R
COFLEX	9430UM-0100	9430UM-100 UMAFD BLACK 4"X3.7YD 100R
COFLEX	3100RD-030	3100RD-INTL CFX LATEX RED 1"X5YD 30R
COFLEX	3100WH-030	3100WH-INTL CFX LATEX WHT 1"X5YD 30R
COFLEX	5100BL-030	5100BL-INTL COFLEX NL BLUE 1"X5YD 30R/C
COFLEX	5150RB-048	5150RB-INTL COFLEX NL RAINBOW 1.5X5YD 48
COFLEX	5150RD-048	5150RD-INTL COFLEX NL RED 1.5"X5YD 48R/C
COFLEX	5200NG-036	5200NG-INTL COFLEX NL N.GRN 2"X5YD 36R/C
COFLEX	5400L-018	5400L-INTL COFLEX NL TAN 4"X6.5YD 18R/C
COFLEX	7300TN-024	7300TN-INTL COFLEX MED TAN 3"X5YD 24R/C
COFLEX	9100CP-030	9100CP-INTL COFLEX LF2 CP 1"X5YD 30R/C
COFLEX	9150CP-048	9150CP-INTL COFLEX LF2 CP 1.5"X5YD 48R/C
COFLEX	9300TN-024	9300TN-INTL COFLEX LF2 TAN 3"X5YD 24R/C
COFLEX	9400CP-018	9400CP-INTL COFLEX LF2 CP 4"X5YD 18R/C
COFLEX	ASP-5400L-018	ASP-5400L-018 ANDOFLEX NL TN 4"X6.5
COFLEX	ASP-5400TN-018	ASP-5400TN-018 ANDOFLEX NL TN 4"X5Y

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
4.0	S. Albritton	12-MAY-2025	Updated the D.O.C format and variants listed
4.1	S. Albritton	03OCT2025	Addition of codes