EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company
Single Registration Number *(TBD)*
2510 Conway Ave. St. Paul, MN 55144 USA

hereby declare under our sole responsibility that the following CE marked device(s)

Trade Name*	Coban™ Self-Adherent Wrap (non-sterile)
Intended Purpose	Elastic wrap used to provide compression, support or to secure dressings or devices.
Reference	1581, 1581B, 1581K, 1582, 1582B, 1582K, 1583, 1583B, 1583G, 1583K, 1583R, 1583W, 1584, 1584B, 1584K 1584L, 1584W, 1586
Basic UDI-DI	06082238401010000000016E5

are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

The Authorized European Representative for the concerned device(s) is

3M Deutschland GmbH
Health Care Business
Single Registration Number (TBD)
Carl-Schurz-Str. 1
41453 Neuss, Germany

Dianne Gibbs, Division Regulatory Affairs Manager
3M Company
2510 Conway Ave. St. Paul, MN 55144 USA

13 March 2020
Date

3M and Coban are trademarks of 3M.

THIS DOCUMENT WAS PRINTED ON 13-Mar-2020 12:06 PM

3M Health Care Business

3M Center
2510 Conway Ave, Bldg. 275-5W-06
St. Paul, MN 55144 U.S.A.
651 733 1110

Declaration of Conformity

As Legal Manufacturer
We, 3M Company, 3M Health Care,
3M Center, 2510 Conway Ave, Bldg. 275-5W-06
Saint Paul, MN 55144 USA

hereby declare under our sole responsibility
that the CE marked products to which this declaration relates,

3M™ Coban™ Self-Adherent Wrap

Product numbers:
1583S, 1584S, 1586S

is classified,
per Rule 1 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC
as a Class Is device
and

is in accordance with Annex(es) V (sterilization) and VII of Directive 93/42/EEC, as amended per 2007/47/EC, on the approximation of the laws of the European Union Member States concerning medical devices.

This declaration is made on the basis of the quality assurance certificate CE 00493 delivered by BSI (Notified Body Number 2797)

EU Representative Address
3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss, Germany

Signature: _____ Date: 30 October 2019

Dianne Gibbs
3M Health Care
Division Regulatory Manager
Medical Solutions Division

REG-DOC-05-164709, Coban™ (Sterile, latex containing), Version 5,
Status: Release, Release Date: 10/28/2019 10:41:00 AM CDT

THIS DOCUMENT WAS PRINTED ON 28-Oct-2019 12:11 PM

3M Company

2510 Conway Ave,
St. Paul, MN 55144 U.S.A.
651 733 1110

Declaration of Conformity

As Legal Manufacturer
We, 3M Company,
2510 Conway Ave,
Saint Paul, MN 55144 USA
hereby declare under our sole responsibility
that the CE marked products to which this declaration relates,

3M™ Coban™ Self-Adherent Wrap
Product numbers:
1581, 1582, 1583, 1584, 1586, 1584L
1581B, 1582B, 1583B, 1583G
1583R, 1583W, 1583Y, 1584B, 1583A, 1583N
1584W, 1581K, 1582K, 1583K, 1584K
1584L/S, 1582/S, 1582/W, 1583W, 1583/B, 1584/S

are classified,

per Rule 1 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC

as a Class I device, and

are in accordance with Annex VII of Directive 93/42/EEC, as amended per 2007/47/EC,
on the approximation of the laws of the European Member States concerning medical devices.

EU Representative Address
3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss, Germany

Signature: _____ Date: 3 March 2020

Dianne L. Gibbs
3M Company
Division Regulatory Affairs Manager
Medical Solutions Division

REG-DOC-05-160626, 3M™ Coban™ Self-Adherent Wrap (2020 MDD DOC), Version 8,
Status: Release, Release Date: 02/12/2020 12:39:58 PM CST

THIS DOCUMENT WAS PRINTED ON 3-Mar-2020 10:05 AM

3M Company

2510 Conway Ave,
St. Paul, MN 55144 U.S.A.
651 733 1110

Declaration of Conformity

As Legal Manufacturer
We, 3M Company,
2510 Conway Ave,
Saint Paul, MN 55144 USA
hereby declare under our sole responsibility
that the CE marked products to which this declaration relates,

3M™ Coban™ NL Non-Latex Self-Adherent Wrap
Product numbers:
2081, 20815, 2082, 2083, 2084, 2084K, 2084LK, 2086, 2086K, 2084L,
2081NP, 2081SP, 2082NP, 2083NP, 2083SP, 2084SP, 2082-1X, 2083-1X, 2084-1X, 2086-1X

are classified,
per Rule 1 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC
as a Class I device, and

are in accordance with Annex VII of Directive 93/42/EEC, as amended per 2007/47/EC,
on the approximation of the laws of the European Member States concerning medical devices.

EU Representative Address
3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss, Germany

Signature: _____ Date: 20 February 2020

Dianne L. Gibbs
3M Company
Division Regulatory Affairs Manager
Medical Solutions Division

REG-DOC-05-164696, 3M™ Coban™ NLNS Non-Latex Self Adherent Wrap Declaration of Conformity
DoC(2020 DOC Update), Version 9,
Status: Release, Release Date: 02/18/2020 04:38:08 PM CST

THIS DOCUMENT WAS PRINTED ON 19-Feb-2020 12:11 PM

3M Health Care Business

3M Center
2510 Conway Ave, Bldg. 275-5W-06
St. Paul, MN 55144 U.S.A.
651 733 1110

Declaration of Conformity

As Legal Manufacturer
We, 3M Company, 3M Health Care,
3M Center, 2510 Conway Ave, Bldg. 275-5W-06
Saint Paul, MN 55144 USA

hereby declare under our sole responsibility
that the CE marked products to which this declaration relates,

3M™ Coban™ LF Latex-Free Self-Adherent Wrap

Product numbers:
2082S, 2083S, 2084S, 2086S

is classified,
per Rule 1 of Annex IX of the Medical Device Directive 93/42/EEC, as amended per 2007/47/EC
as a Class Is device
and

is in accordance with Annex(es) V (sterilization) and VII of Directive 93/42/EEC, as amended per 2007/47/EC, on the approximation of the laws of the European Union Member States concerning medical devices.

This declaration is made on the basis of the quality assurance certificate CE 00493 delivered by BSI, Notified Body Number 2797

EU Representative Address
3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss, Germany

Signature: _____ Date: 30 October 2019

Dianne Gibbs
3M Health Care
Division Regulatory Manager
Medical Solutions Division

REG-DOC-05-164695, Coban™ (Sterile, non-latex), Version 6,
Status: Release, Release Date: 10/28/2019 10:51:37 AM CDT

THIS DOCUMENT WAS PRINTED ON 28-Oct-2019 12:14 PM