DOC. TITLE:	Declaration of Conformity - T.E.D. Anti-Embolism Stockings		
DOCUMENT NO:	RE00183490	REVISION:	3

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DECLARATION OF CONFORMITY

MDR: We, Cardinal Health 200 LLC, declare that the products covered in this EU Declaration of Conformity meet the provision of the Medical Device Regulation (EU) 2017/745.

Declaration of Conformity Number	RE00183490
Technical Documentation Number	RE00169407
Manufacturer's Name	Cardinal Health 200, LLC
Manufacturer's Address	3651 Birchwood Drive Waukegan, IL 60085 USA
Single Registration Number	Not yet issued
Authorized Representative's Name and Address	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Notified body's Name and Identification Number	Not Applicable
CE Certificate Number	Not Applicable
Product Category	Anti-Embolism Compression Stockings
Basic UDI-DI	Anti-Embolism Stocking: 06301400000000000000004468 Anti-Embolism Stocking for Continuing Care: 06301400000000000000004366
Product and trade name, product code	See attached Product Code List table provided in Attachment 1.
Intended Purpose	T.E.D. Anti-Embolism Stockings are intended for the following: (1) Prophylaxis against deep venous thrombosis in medical and surgical patients; (2) To provide graduated compression and thus increase venous blood flow in all conditions where this is indicated, including venous disorders and varicose veins; (3) For use in other conditions as directed by a clinician
Classification and Rule	Class I, Rule 1
Common Specifications	Not Applicable
Where appropriate, add applicable Union legislation	Not Applicable
Conformity assessment	Annex IV

SIGNATURE SECTION			
This EU Declaration of Conformity is issued for and on behalf of and under the sole responsibility of the Legal Manufacturer idetfied above.			
Place of Issue	**Mansfield, MA 02048 USA**		
Signature	Kerri LaPlaca *Electronically signed by: Kerri LaPlaca Reason: Approved Date: Apr 27, 2021 16:01 EDT*	**Date**	April 22, 2021
Title/Position	Kerri LaPlaca/ Regulatory Affairs Manager		

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Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE

EC Certificate: *Self Certified*

Class I (non-sterile/non-measuring) Annex IV

3039	T.E.D. Anti-Embolism Stockings Thigh Length with Belt Small, Regular, Size A+	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3071LF	T.E.D. Anti-Embolism Stockings Thigh Length Small, Short, Size A	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3130LF	T.E.D. Anti-Embolism Stockings Thigh Length Small, Regular, Size B	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3144	T.E.D. Anti-Embolism Stockings Thigh Length with Belt Medium, Regular, Size C+	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3180LF	T.E.D. Anti-Embolism Stockings Thigh Length X-Large, Short, Size N	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
3181LF	T.E.D. Anti-Embolism Stockings Thigh Length X-Large, Regular, Size P	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
3182LF	T.E.D. Anti-Embolism Stockings Thigh Length X-Large, Long, Size Q	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007

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Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE

EC Certificate: *Self Certified*

Class I (non-sterile/non-measuring) Annex IV

3183LF	T.E.D. Anti-Embolism Stockings Thigh Length XX-Large, Short, Size R	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
3184LF	T.E.D. Anti-Embolism Stockings Thigh Length XX-Large, Regular, Size S	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
3185LF	T.E.D. Anti-Embolism Stockings Thigh Length XX-Large, Long, Size T	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
3221	T.E.D. Anti-Embolism Stockings Thigh Length with Belt Large, Regular, Size E+	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3222LF	T.E.D. Anti-Embolism Stockings Thigh Length Small, Long, Size C	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3306	T.E.D. Anti-Embolism Stockings Thigh Length with Belt X-Small, Regular, Size AA+	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3310LF	T.E.D. Anti-Embolism Stockings Thigh Length Medium, Short, Size D	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995

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Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE

EC Certificate: *Self Certified*

Class I (non-sterile/non-measuring) Annex IV

3320	T.E.D. Anti-Embolism Stockings Thigh Length with Belt X-Small, Long, Size BB+	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3364	T.E.D. Anti-Embolism Stockings Thigh Length with Belt Small, Long, Size B+	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3416LF	T.E.D. Anti-Embolism Stockings Thigh Length Medium, Regular, Size E	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3449	T.E.D. Anti-Embolism Stockings Thigh Length with Belt Medium, Long, Size D+	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3523	T.E.D. Anti-Embolism Stockings Thigh Length with Belt Large, Long, Size F+	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3549LF	T.E.D. Anti-Embolism Stockings Thigh Length Medium, Long, Size F	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3634LF	T.E.D. Anti-Embolism Stockings Thigh Length Large, Short, Size G	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995

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Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: *Self Certified*						
Class	***I (non-sterile/non-measuring)***	***Annex IV***				
3728LF	T.E.D. Anti-Embolism Stockings Thigh Length Large, Regular, Size H	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3856LF	T.E.D. Anti-Embolism Stockings Thigh Length Large, Long, Size J	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3922	T.E.D. Anti-Embolism Stockings Thigh Length with Belt X-Large, Regular, Size G+	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
3995	T.E.D. Anti-Embolism Stockings Thigh Length with Belt X-Large, Long, Size H+	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
4010LF	T.E.D. Anti-Embolism Stockings Thigh Length X-Large, Short, Size K	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
4114LF	T.E.D. Anti-Embolism Stockings Thigh Length X-Large, Regular, Size L	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
4216LF	T.E.D. Anti-Embolism Stockings Thigh Length X-Large, Long, Size M	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007

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Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: *Self Certified*						
Class	***I (non-sterile/non-measuring)***	***Annex IV***				
4265	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Beige, Small Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4271	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Beige, Medium Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4278	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length, White, Small, Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4279	T.E.D. Anti-Embolism Stockings for Continuing Care Knee Length, White, Medium, Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4280	T.E.D. Anti-Embolism Stockings for Continuing Care Knee Length, White, Large, Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4281	T.E.D. Anti-Embolism Stockings for Continuing Care Knee Length, White X-Large, Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4282	T.E.D. Anti-Embolism Stockings for Continuing Care Knee Length, White Small, Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012

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Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE

EC Certificate: *Self Certified*

Class I (non-sterile/non-measuring) Annex IV

4283	T.E.D. Anti-Embolism Stockings for Continuing Care Knee Length, White Medium, Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4284	T.E.D. Anti-Embolism Stockings for Continuing Care Knee Length, White Small, Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4285	T.E.D. Anti-Embolism Stockings for Continuing Care Knee Length, White X-Large, Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4289	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Beige, Large Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4296	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Beige, X-Large Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4297	T.E.D. Anti-Embolism Stockings for Continuing Care Thigh Length, White Small, Short	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4298	T.E.D. Anti-Embolism Stockings for Continuing Care Thigh Length, White Medium, Short	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012

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Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: *Self Certified*						
Class	***I (non-sterile/non-measuring)***	***Annex IV***				
4299	T.E.D. Anti-Embolism Stockings for Continuing Care Thigh Length, White Large, Short	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4300	T.E.D. Anti-Embolism Stockings for Continuing Care Thigh Length, White Small, Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4301	T.E.D. Anti-Embolism Stockings for Continuing Care Thigh Length, White Medium, Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4302	T.E.D. Anti-Embolism Stockings for Continuing Care Thigh Length, White Large, Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4303	T.E.D. Anti-Embolism Stockings for Continuing Care Thigh Length, White Small, Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4304	T.E.D. Anti-Embolism Stockings for Continuing Care Thigh Length, White Medium, Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012
4305	T.E.D. Anti-Embolism Stockings for Continuing Care Thigh Length, White Large, Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/9/2012

Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: *Self Certified*						
Class ***I (non-sterile/non-measuring)*** ***Annex IV***						
4317	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Beige, Small Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4323	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Beige, Medium Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4335	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Beige, Large Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4344	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Beige, X-Large Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4434	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Black, Small Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4435	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Black, Medium Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4436	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Black,Large Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015

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Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE

EC Certificate: *Self Certified*

Class I (non-sterile/non-measuring) Annex IV

4437	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Black, X-Large Regular	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4572	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Black,Small Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4573	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Black,Medium Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4574	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Black,Large Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
4575	T.E.D. Anti-Embolism Stockings for Continuing Care, Knee Length Black, X-Large Long	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	8/17/2015
7071	T.E.D. Anti-Embolism Stockings Knee Length Small, Regular, Size A-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
7115	T.E.D. Anti-Embolism Stockings Knee Length Medium, Regular, Size C-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995

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Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE

EC Certificate: *Self Certified*

Class I (non-sterile/non-measuring) Annex IV

7203	T.E.D. Anti-Embolism Stockings Knee Length Large, Regular, Size E-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
7339	T.E.D. Anti-Embolism Stockings Knee Length Small, Long, Size B-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
7470LF	T.E.D. Anti-Embolism Stockings Knee Length XX-Large, Regular, Size J-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
7471LF	T.E.D. Anti-Embolism Stockings Knee Length XX-Large, Long, Size K-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
7472LF	T.E.D. Anti-Embolism Stockings Knee Length XXX-Large, Regular, Size L-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
7473LF	T.E.D. Anti-Embolism Stockings Knee Length XXX-Large, Long, Size M-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	2/28/2007
7480	T.E.D. Anti-Embolism Stockings Knee Length Medium, Long, Size D-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995

Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: *Self Certified*						
Class ***I (non-sterile/non-measuring)*** ***Annex IV***						
7499	T.E.D. Anti-Embolism Stockings Knee Length, Small, Short, Size AA-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	01/22/2021
7594	T.E.D. Anti-Embolism Stockings Knee Length Large, Long, Size F-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
7604	T.E.D. Anti-Embolism Stockings Knee Length X-Large, Regular, Size G-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995
7802	T.E.D. Anti-Embolism Stockings Knee Length X-Large, Long, Size H-	No	Non	Compression/pressure sock/stocking, single-use [30878]	1	11/30/1995

Document to be digitally signed’

Final Audit Report 2021-04-27

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By:	Kerri LaPlaca (kerri.laplaca@cardinalhealth.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAepgvkopLi6X2o5M8rf-i_UVvg1INiAzg

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