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

CardinalHealth

# 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<br>Anti-Embolism Stocking for Continuing Care:<br>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:<br>(1) Prophylaxis against deep venous thrombosis in medical and surgical patients;<br>(2) To provide graduated compression and thus increase venous blood flow in all conditions where this is indicated, including venous disorders and varicose veins;<br>(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 | | |

***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 |

***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 |

***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 |

***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 |

***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 |

***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 |

***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

| | |
|---|---|
| Created: | 2021-04-27 |
| By: | Kerri LaPlaca (kerri.laplaca@cardinalhealth.com) |
| Status: | Signed |
| Transaction ID: | CBJCHBCAABAAepgvkopLi6X2o5M8rf-i_UVvg1INiAzg |

## "Document to be digitally signed’" History

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