



CE DECLARATION OF CONFORMITY

(Class I Medical Devices)

Danish company Pil-Pak A/S, with address in Fuglebakvej, 3E in Kastrup, Denmark, VAT number 26541115, with technical responsible Jesper Larsson, email: jesper@pil-pak.dk and phone number: 045 32513744

Declares:

That the medical devices manufactured by them (see Annex I), graduated compression stockings, comply with:

- a) The requirements laid down in Annex I, Directive 93/42/EEC June 14, in its current wording;
- b) Decree -Law n ° 145/2009 June 17;
- c) The Standard CEN / TR 15831 " Method for testing in medical compression hosiery ";
- d) NP EN ISO 13485-2004 - MD - Requirements for regulatory purposes.

In the aspects that apply to them, so it does not compromise the clinical condition or the safety of patients, or even the safety and health of users or, where applicable, other persons, when used under the conditions and for the purposes specified, considering that possible risks associated with the intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high degree of protection of health and safety.

Undertakes to:

Create and maintain a systematic procedure to review experience gained from devices in the post-production phase including the provisions referred to in Annex XVI of the Decree -Law n ° 145/2009 June of 17. Implement appropriate means to apply any necessary corrective actions, taking into account the nature and risks associated with the product and notify the Competent Authority about their incidents, such as:

Any malfunction, failure or deterioration in the characteristics or functional performance , and any inaccuracy , omission or inadequacy in the labelling or the instructions for use of a device that is likely to cause or have caused the death or serious deterioration of health status of a patient , user or third party;

Any indirect problem, as a result of an incorrect medical decision related to a medical device, when used according to the instructions provided by the manufacturer;

Any technical or medical reason related to the characteristics or the performance of a device that for the reasons referred above, has led to security corrective action in the Scandinavian market with devices of the same type made by the manufacturer.

Other information that the experience demonstrates they should be notified. Establish the technical documentation and keep it updated, including this statement available to the Competent Authority for the purposes of inspection for five years from the last date of medical device manufacture.

Date: 13/06/2015


Technical Responsible

Art number	Art	Art:	Size	
1503	1503 02 p	With Window	40-42	5712843503826
1503	1503 04 p	With Window	43-45	5712843503840
1503	1503 05 p	With Window	46-48	5712843503857
1504	1504 08 p	Black grey stripes	34-36	5712843504885
1504	1504 09 p	Black grey stripes	37-39	5712843504892
1504	1504 02 p	Black grey stripes	40-42	5712843504823
1504	1504 04 p	Black grey stripes	43-45	5712843504847
1504	1504 05 p	Black grey stripes	46-48	5712843504854
1504-1	1504 08 2	White Black Stripes	34-36	5712843504281
1504-1	1504 09 2	White Black Stripes	37-39	5712843504298
1504-1	1504 02 2	White Black Stripes	40-42	5712843504229
1504-3	1504 08 1	Black blue stripes	34-36	5712843504182
1504-3	1504 09 1	Black blue stripes	37-39	5712843504199
1504-3	1504 02 1	Black blue stripes	40-42	5712843504120
1504-5	1504 09 4	White with green stripes	37-39	5712843504496
1504-5	1504 02 4	White with green stripes	40-42	5712843504427
1504-7	1504 08 6	White with turquoise stripes	34-36	5712843504687
1504-7	1504 09 6	White with turquoise stripes	37-39	5712843504694
1504-7	1504 02 6	White with turquoise stripes	40-42	5712843504625
1504-8	1504 09 7	White with blue stripes	37-39	5712843504793
1504-8	1504 02 7	White with blue stripes	40-42	5712843504724
1510	1510 09 b	White	37-39	5712843510992
1510	1510 02 b	White	40-42	5712843510923
1510	1510 04 b	White	43-45	5712843510947
1510	1510 05 b	White	46-48	5712843510954
1510-1	1510 08 p	Black	34-36	5712843510886
1510-1	1510 09 p	Black	37-39	5712843510893
1510-1	1510 02 p	Black	40-42	5712843510824
1510-1	1510 04 p	Black	43-45	5712843510848
1510-1	1510 05 p	Black	46-48	5712843510855
1514	1514 09 3	Running socks/ Orange	35-39	5712843514891
1514	1514 02 3	Running socks/ Orange	39-43	5712843514839
1514	1514 04 3	Running socks/ Orange	43-47	5712843514853
1514-1	1514 09 2	Running socks/ Green	35-39	5712843514297
1514-1	1514 02 2	Running socks/ Green	39-43	5712843514235
1514-1	1514 04 2	Running socks/ Green	43-47	5712843514259
1514-2	1514 09 4	Running socks/light Green	35-39	5712843514495
1514-2	1514 02 4	Running socks/light Green	39-43	5712843514433
1514-2	1514 04 4	Running socks/light Green	43-47	5712843514457
1517	1517 02 p	With Stripes	40-42	5712843517823
1517	1517 04 p	With Stripes	43-45	5712843517847
1517	1517 05 p	With Stripes	46-48	5712843517854
1518	1518 09 1	With Green black stripes	37-39	5712843518196
1518	1518 02 1	With Green black stripes	40-42	5712843518127
1518	1518 04 1	With Green black stripes	43-45	5712843518141
1518-1	1518 09 2	With Pink black stripes	37-39	5712843518295
1518-1	1518 02 2	With Pink black stripes	40-42	5712843518226
1518-1	1518 04 2	With Pink black stripes	43-45	5712843518240
1520	1520 08 p	With Dots	34-36	5712843520885
1520	1520 09 p	With Dots	37-39	5712843520892
1520	1520 02 p	With Dots	40-42	5712843520823
1520	1520 04 p	With Dots	43-45	5712843520847

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7009	1534 09 p	Many Color (new model)	37-39	5712843534899
7009	1534 02 p	Many Color (new model)	40-42	5712843534820
7009	1534 04 p	Many Color (new model)	43-45	5712843534844
7010 B	1535 09 P	Tribel (new model)	37-39	5712843535896
7010 B	1535 02 P	Tribel (new model)	40-42	5712843535827
7012	1536 08 b	With Ambulance (new model)	34-36	5712843536985
7012	1536 09 b	With Ambulance (new model)	37-39	5712843536992
7012	1536 02 b	With Ambulance (new model)	40-42	5712843536923
7012	1536 04 b	With Ambulance (new model)	43-45	5712843536947
7013	1537 09 2	Pink Harlequin (new model)	37-39	5712843537296
7013	1537 02 2	Pink Harlequin (new model)	40-42	5712843537227
7013	1537 04 2	Pink Harlequin (new model)	43-45	5712843537241
7014	5587 08 1	Blue with Flowers (new model)	34-36	5712843587185
7014	5587 09 1	Blue with Flowers (new model)	37-39	5712843587192
7014	5587 02 1	Blue with Flowers (new model)	40-42	5712843587123
7014	5587 04 1	Blue with Flowers (new model)	43-45	5712843587147
1523	1523 08 p	Black Bamboe (new model)	34-36	5712843523886
1523	1523 09 p	Black Bamboe (new model)	37-39	5712843523893
1523	1523 02 p	Black Bamboe (new model)	40-42	5712843523824
1523	1523 04 p	Black Bamboe (new model)	43-45	5712843523848
1523	1523 05 p	Black Bamboe (new model)	46-48	5712843523855
1523-1	1523 08 1	Red Bamboe (new model)	34-36	5712843523183
1523-1	1523 09 1	Red Bamboe (new model)	37-39	5712843523190
1523-1	1523 02 1	Red Bamboe (new model)	40-42	5712843523121
1523-1	1523 04 1	Red Bamboe (new model)	43-45	5712843523145
1523-2	1523 08 2	Gray Bamboe (new model)	34-36	5712843523282
1523-2	1523 09 2	Gray Bamboe (new model)	37-39	5712843523299
1523-2	1523 02 2	Gray Bamboe (new model)	40-42	5712843523220
1523-2	1523 04 2	Gray Bamboe (new model)	43-45	5712843523244
1523-3	1523 08 4	Blue Bamboe (new model)	34-36	5712843523480
1523-3	1523 09 4	Blue Bamboe (new model)	37-39	5712843523497
1523-3	1523 02 4	Blue Bamboe (new model)	40-42	5712843523428
1523-3	1523 04 4	Blue Bamboe (new model)	43-45	5712843523442
1523-4	1523 09 3	Green Bamboe (new model)	37-39	5712843523398
1523-4	1523 02 3	Green Bamboe (new model)	40-42	5712843523329
1533	1533 09 p	Black without toe	37-39	5712843533892
1533	1533 02 p	Black without toe	40-42	5712843533823
1533	1533 04 p	Black without toe	43-45	5712843533847
1533-1	1533 09 b	White without toe	37-39	5712843533991
1533-1	1533 02 b	White without toe	40-42	5712843533922
1533-1	1533 04 b	White without toe	43-45	5712843533946
1581	1581 09 p	Black with Coolmax	35-39	5712843581893
1581	1581 02 p	Black with Coolmax	39-43	5712843581831
1581	1581 04 p	Black with Coolmax	43-47	5712843581855
3023	3023 09 p	Ankle socks with Coolmax	35-39	5712843023898
3023	3023 02 p	Ankle socks with Coolmax	39-43	5712843023836
3023	3023 04 p	Ankle socks with Coolmax	43-47	5712843023850
7007	1570 09 8	Grey/Pink	37-39	5712843570897
7007	1570 02 8	Grey/Pink	40-42	5712843570828
7007	1570 04 8	Grey/Pink	43-45	5712843570842
7008	1570 09 11	Grey/Green	37-39	5712843570194
7008	1570 02 11	Grey/Green	40-42	5712843570125
7008	1570 04 11	Grey/Green	43-45	5712843570149

Nylon:

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6500	6500 01 1	Compression Socks, Nature	34-37	5712843500115
6500	6500 02 1	Compression Socks, Nature	37-39	5712843500122
6500	6500 04 1	Compression Socks, Nature	39-42	5712843500146
6500-1	6500 01 p	Compression Socks, Black	34-37	5712843500818
6500-1	6500 02 p	Compression Socks, Black	37-39	5712843500825
6500-1	6500 04 p	Compression Socks, Black	39-42	5712843500849
6501	6501 S P	Stay up, Black	Small	5712843501815
6501	6501 M P	Stay up, Black	Medium	5712843501822
6501	6501 L P	Stay up, Black	Large	5712843501839
6501	6501 XL P	Stay up, Black	Xlarge	5712843501846
6501-1	6501 S 1	Stay up, Nature	Small	5712843501112
6501-1	6501 M 1	Stay up, Nature	Medium	5712843501129
6501-1	6501 L 1	Stay up, Nature	Large	5712843501136
6501-1	6501 XL 1	Stay up, Nature	Xlarge	5712843501143
6505	6505 S P	Tights, Black	Small	5712843505813
6505	6505 M P	Tights, Black	Medium	5712843505820
6505	6505 L P	Tights, Black	Large	5712843505837
6505	6505 XL	Tights, Black	Xlarge	5712843505844
6505	6505 XXL P	Tights, Black	XXLarge	5712843505851
6505-1	6505-1	Tights, Nature	Small	5712843505110
6505-1	6505-1	Tights, Nature	Medium	5712843505127
6505-1	6505-1	Tights, Nature	Large	5712843505134
6505-1	6505-1	Tights, Nature	Xlarge	5712843505141
6505-1	6505-1	Tights, Nature	XXLarge	5712843505158
6506	6506 S 1	Maternity Tights, Nature	Small	5712843506117
6506	6506 M 1	Maternity Tights, Nature	Medium	5712843506124
6506	6506 L 1	Maternity Tights, Nature	Large	5712843506131
6506	6506 XL 1	Maternity Tights, Nature	Xlarge	5712843506148
6506	6506 XXL 1	Maternity Tights, Nature	XXLarge	5712843506155
6506-2	6506-2	Maternity Tights, Black	Small	5712843506810
6506-2	6506-2	Maternity Tights, Black	Medium	5712843506827
6506-2	6506-2	Maternity Tights, Black	Large	5712843506834
6506-2	6506-2	Maternity Tights, Black	Xlarge	5712843506841
6506-2	6506-2	Maternity Tights, Black	XXLarge	5712843506858
Class 2 socks:				
6509	6509 ss p	Class 2 sock/Black	Small	5712843509811
6509	6509 mm p	Class 2 sock/Black	Medium	5712843509828
6509	6509 ll p	Class 2 sock/Black	Large	5712843509828
6509	6509 xl p	Class 2 sock/Black	Xlarge	5712843509842
6509-1	6509 ss 1	Class 2 sock/Beige (new)	Small	5712843509118
6509-1	6509 mm 1	Class 2 sock/Beige (new)	Medium	5712843509125
6509-1	6509 ll 1	Class 2 sock/Beige (new)	Large	5712843509132
6509-1	6509 xl 1	Class 2 sock /Beige (new)	Xlarge	5712843509149
6510	7510 ss p	Class 2 sock/Black open toe (new)	Small	5712843510817
6510	7510 mm p	Class 2 sock/Black open toe (new)	Medium	5712843751821
6510	7510 ll p	Class 2 sock/Black open toe (new)	Large	5712843510831
6510	7510 xl p	Class 2 sock/Black open toe (new)	Xlarge	5712843751845
6510-1	7510 ss 1	Class 2 sock/Beige open toe (new)	Small	5712843510114
6510-1	7510 mm 1	Class 2 sock/Beige open toe (new)	Medium	5712843510121
6510-1	7510 ll 1	Class 2 sock/Beige open toe (new)	Large	5712843510138
6510-1	7510 xl 1	Class 2 sock/Beige open toe (new)	Xlarge	5712843510145
Diabetic socks:				
5550	5550 08 p	Diabetic sock, Black	36/37	5712843555870
5550	5550 09 p	Diabetic sock, Black	38/39	5712843555887
5550	5550 02 p	Diabetic sock, Black	40/41	5712843555894
5550	1550 03 p	Diabetic sock, Black	41/42	5712843155834

5550	1550 04 p	Diabetic sock, Black	43/44	5712843155841
5550	1550 05 p	Diabetic sock, Black	45/46	5712843155858
		<u>Flight socks in micropolyester</u>		
1502	1502 09 p	Black	35-39	5712843502898
1502	1502 03 p	Black	39-43	5712843502836
1502	1502 05 p	Black	43-47	5712843502850
1502-3	1502 09 p	Dark Grey	35-39	5712843502294
1502-3	1502 03 p	Dark Grey	39-43	5712843502232
1502-3	1502 05 p	Dark Grey	43-47	5712843502249
1502-1	1502 09 p	White	35-39	5712843502997
1502-1	1502 03 p	White	39-43	5712843502935
1502-1	1502 05 p	White	43-47	5712843502942
1502-2	1502 09 p	Beige	35-39	5712843502690
1502-2	1502 03 p	Beige	39-43	5712843502638
1502-2	1502 05 p	Beige	43-47	5712843502645

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GF

1516	6557 s	compression tube	35-39	5712843557812
1516	6557 m	compression tube	39-43	5712843557829
1516	6557 L	compression tube	43-47	5712843557836

Tight High AGH Class 2

140 Denin

With toe

2010	7505-P	Black	S	5712843010812
2010	7505	Black	M	5712843010829
2010	7505	Black	L	5712843010836
2010	7505	Black	XL	5712843010843
2010	7505	Black	XXL	5712843010850

2010-1	7505-1	Beige	S	5712843010119
2010-1	7505	Beige	M	5712843010126
2010-1	7505	Beige	L	5712843010133
2010-1	7505	Beige	XL	5712843010140
2010-1	7505	Beige	XXL	5712843010157

Without toe

2020	7504-P	Black	S	5712843020811
2020	7504	Black	M	5712843020828
2020	7504	Black	L	5712843020835
2020	7504	Black	XL	5712843020842
2020	7504	Black	XXL	5712843020859

2020-1	7504-1	Beige	S	5712843020118
2020-1	7504	Beige	M	5712843020125
2020-1	7504	Beige	L	5712843020132
2020-1	7504	Beige	XL	5712843020149
2020-1	7504	Beige	XXL	5712843020156

Pantyhose AT Class 2

140 denin

7200-2	5568-P	Fun Stars	34-36	5712843203818
7200-2	5568	Fun Stars	37-39	5712843203825
7200-2	5568	Fun Stars	40-42	5712843203832
7200-2	5568	Fun Stars	43-45	5712843203849
7200-3	5568-1	Fun Stars Colour	34-36	5712843203115
7200-3	5568	Fun Stars Colour	37-39	5712843203122
7200-3	5568	Fun Stars Colour	40-42	5712843203139
7200-3	5568	Fun Stars Colour	43-45	5712843203146
7200-4	5569-2	Fun Hearts Red	34-36	5712843204211
7200-4	5569	Fun Hearts Red	37-39	5712843204228
7200-4	5569	Fun Hearts Red	40-42	5712843204235
7200-4	5569	Fun Hearts Red	43-45	5712843204242
7300-1	5570-P	ZigZag Black	34-36	5712843301514
7300-1	5570	ZigZag Black	37-39	5712843301521
7300-1	5570	ZigZag Black	40-42	5712843301538
7300-1	5570	ZigZag Black	43-45	5712843301545
7300-2	5570-5	ZigZag Grey	34-36	5712843302818
7300-2	5570	ZigZag Grey	37-39	5712843302825
7300-2	5570	ZigZag Grey	40-42	5712843303839
7300-2	5570	ZigZag Grey	43-45	5712843303846
Bamboo				
7400-1	5571-1	Small Stripes Black	37-39	5712843571122
7400-1	5571	Small Stripes Black	40-42	5712843571139
7400-1	5571	Small Stripes Black	43-45	5712843571146
7400-1	5571	Small Stripes Black	46-48	5712843571153
7400-2	5571-2	Small Stripes Grey	37-39	5712843571221
7400-2	5571	Small Stripes Grey	40-42	5712843571238
7400-2	5571	Small Stripes Grey	43-45	5712843571245
7400-2	5571	Small Stripes Grey	46-48	5712843571252
7400-3	5571-3	Small Stripes Navy	37-39	5712843571320
7400-3	5571	Small Stripes Navy	40-42	5712843571337
7400-3	5571	Small Stripes Navy	43-45	5712843571344
7400-3	5571	Small Stripes Navy	46-48	5712843571351
7400-4	5571-4	Small Stripes Army	37-39	5712843571429
7400-4	5571	Small Stripes Army	40-42	5712843571436
7400-4	5571	Small Stripes Army	43-45	5712843571443
7400-4	5571	Small Stripes Army	46-48	5712843571450
7400-5	5571-5	Small Stripes Purple	37-39	5712843571528
7400-5	5571	Small Stripes Purple	40-42	5712843571535
7400-5	5571	Small Stripes Purple	43-45	5712843571542
7400-5	5571	Small Stripes Purple	46-48	5712843571559
7500-3	5572	Block Stripes Navy	34-36	5712843500115
7500-3	5572	Block Stripes Navy	37-39	5712843500122
7500-3	5572	Block Stripes Navy	40-42	5712843500139
7500-3	5572	Block Stripes Navy	43-45	5712843500146

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