

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac Kugledynen® Classic Protac Kugledynen® Flexible Protac Kugledynen® Calm	Protac Kugledynen® Combi Protac Granulatdynen™
Type / Model:	See TD 2.1 page 1 – 5.	
Class:	Class 1 – according to regulation (EU) 2017/745	

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 10.03.21



Pia Christiansen
Managing Director

Dok. Nr.: TD 2.1	Emne: Declaration of Conformity - Appendix	Version: 2	Dato: 18.03.2020	Opdateret 07.10.2020
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Protac Kugledynen® Classic

Nummer	Beskrivelse	UDI
100-101-J-85	Protac Kugledynen® Junior, 3,5 kg	5714882006115
100-101-V-10-85	Protac Kugledynen® 10 kg	5714882006122
100-101-V-220-10-85	Protac Kugledynen® 10 kg, 220 cm	5714882006139
100-101-V-220-85	Protac Kugledynen® 8 kg, 220 cm	5714882006146
100-101-V-85	Protac Kugledynen® 7 kg	5714882006153
100-102-J-85	Protac Kugledynen® Junior, 3,5 kg	5714882006160
100-102-V-10-85	Protac Kugledynen® 10 kg	5714882006177
100-102-V-220-85	Protac Kugledynen® 8 kg, 220 cm	5714882006184
100-102-V-85	Protac Kugledynen® 7 kg	5714882006191
100-115-V-220-85	Protac Kugledynen® 6 kg, 220 cm	5714882030882
100-115-V-85	Protac Kugledynen® 5 kg	5714882030899
100-126-V-220-85	Protac Kugledynen® 6 kg, 220 cm	5714882030905
100-126-V-85	Protac Kugledynen® 5 kg	5714882030646
100-107-B-85	Protac Kugledynen® Baby, 1,5 kg	5714882006245
100-107-B-85_KK	Protac Kugledynen® Baby, 1,5 kg, KK	5714882006252
100-107-P	Protac Kugledynen® Præmatur, 0,5 kg	5714882006269
100-108-B-85_KK	Protac Kugledynen® Baby, 1,5 kg, KK	5714882006276

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Protac Kugledynen® Flexible

Nummer	Beskrivelse	UDI
100-201-J-85	Protac Kugledynen® Flexible, Junior, 3,5 kg	5714882006368
100-201-J-85_KK	Protac Kugledynen® Flexible, Junior, 3,5 kg	5714882006375
100-201-V-10-220-85	Protac Kugledynen® Flexible, 11 kg, 220 cm	5714882006399
100-201-V-10-85	Protac Kugledynen® Flexible, 10 kg	5714882006405
100-201-V-10-85_KK	Protac Kugledynen® Flexible, 11 kg, 220 cm, KK	5714882006412
100-201-V-12-85	Protac Kugledynen® Flexible, 12 kg	5714882006429
100-201-V-12-85_KK	Protac Kugledynen® Flexible, 12 kg, KK	5714882006436
100-201-V-220-85	Protac Kugledynen® Flexible, 8 kg, 220 cm	5714882006443
100-201-V-220-85_KK	Protac Kugledynen® Flexible, 8 kg, 220 cm, KK	5714882006450
100-201-V-85	Protac Kugledynen® Flexible, 7 kg	5714882006467
100-201-V-85_KK	Protac Kugledynen® Flexible, 7 kg, KK	5714882006474
100-202-J-85	Protac Kugledynen® Flexible, Junior, 3,5 kg	5714882006481
100-202-J-85_KK	Protac Kugledynen® Flexible, Junior, 3,5 kg, KK	5714882006498
100-202-V-10-220-85	Protac Kugledynen® Flexible, 11 kg, 220 cm	5714882006504
100-202-V-10-85	Protac Kugledynen® Flexible, 10 kg	5714882006511
100-202-V-10-85_KK	Protac Kugledynen® Flexible, 10 kg,	5714882006528
100-202-V-12-85_KK	Protac Kugledynen® Flexible, 12 kg, KK	5714882006535
100-202-V-220-85	Protac Kugledynen® Flexible, 8 kg, 220 cm	5714882006542
100-202-V-220-85_KK	Protac Kugledynen® Flexible, 8 kg, 220 cm, KK	5714882006559
100-202-V-85	Protac Kugledynen® Flexible, 7 kg	5714882006566
100-202-V-85_KK	Protac Kugledynen® Flexible, 7 kg, KK	5714882006573
100-215-V-220-85	Protac Kugledynen® Flexible, 7 kg, 220 cm	5714882030646
100-215-V-85	Protac Kugledynen® Flexible, 6 kg	5714882030653
100-217-V-220-85_KK	Protac Kugledynen® Flexible, 7 kg, 220 cm, KK	5714882030660
100-217-V-85_KK	Protac Kugledynen® Flexible, 6 kg, KK	5714882030677
100-226-V-220-85	Protac Kugledynen® Flexible, 7kg, 220 cm	5714882030769
100-226-V-85	Protac Kugledynen® Flexible, 6 kg	5714882030776
100-228-V-220-85_KK	Protac Kugledynen® Flexible, 7 kg, 220 cm, KK	5714882030783
100-228-V-85_KK	Protac Kugledynen® Flexible, 6 kg, KK	5714882030790

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Protac Kugledynen® Calm

Nummer	Beskrivelse	UDI
100-321-J-85	Protac Kugledynen® Calm Junior	5714882006740
100-321-J-85_KK	Protac Kugledynen® Calm Junior, 3,5 kg	5714882006757
100-321-V-10-220-85	Protac Kugledynen® Calm, 11 kg, 220cm	5714882006764
100-321-V-10-85	Protac Kugledynen® Calm, 10 kg	5714882006771
100-321-V-10-85_KK	Protac Kugledynen® Calm, 10 kg, KK	5714882006788
100-321-V-12-85_KK	Protac Kugledynen® Calm, 12 kg, KK	5714882006795
100-321-V-4-220-85	Protac Kugledynen® Calm, 5 kg, 220 cm	5714882006801
100-321-V-4-85	Protac Kugledynen® Calm, 4 kg	5714882006818
100-321-V-4-85_KK	Protac Kugledynen® Calm, 4 kg, KK	5714882006825
100-321-V-7-220-85	Protac Kugledynen® Calm, 7 kg, 220 cm	5714882006832
100-321-V-7-85	Protac Kugledynen® Calm, 7 kg	5714882006849
100-321-V-7-85_KK	Protac Kugledynen® Calm, 7 kg, KK	5714882006856
100-322-J-85	Protac Kugledynen® Calm Junior, 3,5 kg	5714882006870
100-322-J-85_KK	Protac Kugledynen® Calm Junior, 3,5 kg, KK	5714882006887
100-322-V-10-220-85	Protac Kugledynen® Calm, 11 kg, 220 cm	5714882006894
100-322-V-10-85	Protac Kugledynen® Calm, 10 kg	5714882006900
100-322-V-10-85_KK	Protac Kugledynen® Calm, 10 kg, KK	5714882006917
100-322-V-12-85_KK	Protac Kugledynen® Calm, 12 kg, KK	5714882006924
100-322-V-4-220-85	Protac Kugledynen® Calm, 5 kg, 220 cm	5714882006931
100-322-V-4-85	Protac Kugledynen® Calm, 4 kg	5714882006948
100-322-V-4-85_KK	Protac Kugledynen® Calm, 4 kg, KK	5714882006955
100-322-V-7-220-85	Protac Kugledynen® Calm, 7 kg, 220 cm	5714882006962
100-322-V-7-85	Protac Kugledynen® Calm, 7 kg	5714882006979
100-322-V-7-85_KK	Protac Kugledynen® Calm, 7 kg, KK	5714882006986

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Protac Granulatdynen™

Nummer	Beskrivelse	UDI
100-219-V-220-85	Protac Granulatdynen™ Flexible, 3,5 kg, 220 cm	5714882030684
100-219-V-220-85_KK	Protac Granulatdynen™ Flexible, 3,5 kg, 220 cm, KK	5714882030691
100-219-V-85	Protac Granulatdynen™ Flexible, 3 kg	5714882030707
100-219-V-85_KK	Protac Granulatdynen™ Flexible, 3 kg, KK	5714882030714
100-220-V-220-85	Protac Granulatdynen™ Flexible, 3,5 kg, 220 cm	5714882030721
100-220-V-220-85_KK	Protac Granulatdynen™ Flexible, 3,5 kg, 220 cm, KK	5714882030738
100-220-V-85	Protac Granulatdynen™ Flexible, 3 kg	5714882030745
100-220-V-85_KK	Protac Granulatdynen™ Flexible, 3 kg, KK	5714882030752
100-419-V-220-85	Protac Granulatdynen™ 5,5 kg, 220 cm	5714882006993
100-419-V-220-85_KK	Protac Granulatdynen™ 5,5 kg, 220 cm, KK	5714882007006
100-419-V-85	Protac Granulatdynen™ 5 kg	5714882007013
100-419-V-85_KK	Protac Granulatdynen™ 5 kg, KK	5714882007020
100-429-V-220-85	Protac Granulatdynen™ 5,5 kg, 220 cm	5714882007037
100-429-V-220-85_KK	Protac Granulatdynen™ 5,5 kg, 220 cm, KK	5714882007044
100-429-V-85	Protac Granulatdynen™ 5 kg	5714882007051
100-429-V-85_KK	Protac Granulatdynen™ 5 kg, KK	5714882007068

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac Kuglepuden [®]
Type / Model:	See TD 2.1 page 1 – 2.
Class:	Class 1 – according to regulation (EU) 2017/745

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 07.05.21



Pia Christiansen
Managing Director

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Protac Kuglepuden®

Nummer	Beskrivelse	UDI
200-201-10-30	Protac Kuglepuden, Aqua, 40x40 cm	5714882007686
200-201-10-40	Protac Kuglepuden, Lime, 40x40 cm*	5714882007709
200-201-10-80	Protac Kuglepuden, Mørke Grå, 40x40 cm	5714882007822
200-201-10-4-30	Protac Kuglepuden, Aqua, 40x40 cm, 4-delt	5714882007747
200-201-10-4-80	Protac Kuglepuden, Dark Grey, 40x40 cm, 4-delt	5714882007808
200-201-11-80	Protac Kuglepuden, Dark Grey,	5714882007853
200-201-11-L-80	Protac Kuglepuden, Dark Grey, L,	5714882007846
200-201-12-80	Protac Kuglepuden, Dark Grey, 30x35 cm	5714882007860
200-201-13-80	Protac Kuglepuden, Dark Grey, 30x30 cm	5714882007884
200-201-14-80	Protac Kuglepuden, Dark Grey, 35x35 cm	5714882007891
200-201-15-30	Protac Kuglepuden, Aqua, 40x40 cm	5714882007907
200-201-15-80	Protac Kuglepuden, Dark Grey, 40x40 cm	5714882007969
200-202-10-30	Protac Kuglepuden, Aqua, 40x40 cm	5714882007983
200-202-10-80	Protac Kuglepuden, Dark Grey, 40x40 cm.	5714882008126
200-202-10-4-30	Protac Kuglepuden, Aqua, 40x40 cm. 4-delt	5714882008041
200-202-10-4-80	Protac Kuglepuden, Dark Grey, 40x40 cm. 4-delt	5714882008102
200-202-11-80	Protac Kuglepuden, Dark Grey, Høj barnestol	5714882008140
200-202-12-80	Protac Kuglepuden, Dark Grey, 30x35 cm	5714882008157
200-202-13-80	Protac Kuglepuden, Dark Grey, 30x30 cm.	5714882008171
200-202-14-80	Protac Kuglepuden, Dark Grey, 35x35 cm	5714882008188
200-202-15-30	Protac Kuglepuden, Aqua, 40x40 cm	5714882008195
200-202-15-80	Protac Kuglepuden, Dark Grey, 40x40 cm	5714882008256

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Protac Kuglepuden®

Nummer	Beskrivelse	UDI
200-201-10-30_KK	Protac Kuglepuden, Aqua, 40x40 cm	5714882007693
200-201-10-40_KK	Protac Kuglepuden, Lime, 40x40 cm	5714882007716
200-201-10-41_KK	Protac Kuglepuden, Dusty Green, 40x40 cm	5714882007730
200-201-10-80_KK	Protac Kuglepuden, Dark Grey, 40x40 cm	5714882007839
200-201-10-4-30_KK	Protac Kuglepuden, Aqua, 40x40 cm, 4-delt	5714882007754
200-201-10-4-40_KK	Protac Kuglepuden, Lime, 40x40 cm, 4-delt	5714882007778
200-201-10-4-41_KK	Protac Kuglepude, Dusty Green 40x40 cm, 4-delt	5714882007792
200-201-10-4-80_KK	Protac Kuglepuden, Dark Grey, 40x40 cm, 4-delt	5714882007815
200-201-12-80_KK	Protac Kuglepuden, Dark Grey 30x35 cm	5714882007877
200-201-15-30_KK	Protac Kuglepuden, Aqua, 40x40 cm	5714882007914
200-201-15-40_KK	Protac Kuglepuden, Lime, 40x40 cm	5714882007938
200-201-15-41_KK	Protac Kuglepuden, Dusty Green, 40x40 cm	5714882007952
200-201-15-80_KK	Protac Kuglepuden, Dark Grey, kontorstol 40x40 cm	5714882007976

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac GroundMe[®]
Type / Model:	See TD 2.1 page 1
Class:	Class 1 – according to regulation (EU) 2017/745 – Rule 4.1-1

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 28.04.21



Pia Christiansen
Managing Director

Dok. Nr.: TD 2.1	Emne: Declaration of Conformity - Appendix	Version: 1	Dato: 28.04.21	Opdateret
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Protac GroundMe®

Number	Description	UDI
700-710-10-3820-30	Protac GroundMe®, 10 cm, Aqua	5714882012789
700-710-10-3820-40	Protac GroundMe®, 10 cm, Lime	5714882012802
700-710-10-3820-41	Protac GroundMe®, 10 cm, Dusty Green	5714882012826
700-710-10-3820-80	Protac GroundMe®, 10 cm, Dark Grey	5714882012840
700-710-20-3820-30	Protac GroundMe®, 20 cm, Aqua	5714882012864
700-710-20-3820-40	Protac GroundMe®, 20 cm, Lime	5714882012888
700-710-20-3820-41	Protac GroundMe®, 20 cm, Dusty Green	5714882012901
700-710-20-3820-80	Protac GroundMe®, 20 cm, Dark Grey	5714882012925

Variants

700-710-10-3820-30_KK	Protac GroundMe®, 10 cm, Aqua	5714882012796
700-710-10-3820-40_KK	Protac GroundMe®, 10 cm, Lime	5714882012819
700-710-10-3820-41_KK	Protac GroundMe®, 10 cm, Dusty Green	5714882012833
700-710-10-3820-80_KK	Protac GroundMe®, 10 cm, Dark Grey	5714882012857
700-710-20-3820-30_KK	Protac GroundMe®, 20 cm, Aqua	5714882012871
700-710-20-3820-40_KK	Protac GroundMe®, 20 cm, Lime	5714882012895
700-710-20-3820-41_KK	Protac GroundMe®, 20 cm, Dusty Green	5714882012918
700-710-20-3820-80_KK	Protac GroundMe®, 20 cm, Dark Grey	5714882012932

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac Inkontinensbetræk™
Type / Model:	See TD 2.1 page 1
Class:	Class 1 – according to regulation (EU) 2017/745 – Rule 4.1-1

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 28.04.21

Pia Christiansen

Pia Christiansen
Managing Director

Dok. Nr.: TD 2.1	Emne: Declaration of Conformity - Appendix	Version: 1	Dato: 28.04.21	Opdateret
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Protac Incontinence cover™

Number	Description	UDI
300-302-J	Incontinence Cover, size 100 x 140 cm	5714882010280
300-302-V	Incontinence Cover, size 140 x 200 cm	5714882010310
300-302-V-220	Incontinece Cover, size 140 x 220 cm	5714882010334
300-304-J	Incontinence Cover, w/mesh, size 100 x140 cm	5714882010358
300-304-V	Incontinence Cover, w/mesh, size 140 x 200 cm	5714882010372
300-304-V-220	Incontinence Cover,w/mesh, size 140 x 220 cm	5714882010396
Variants		
300-302-J-KK	Incontinence Cover, size 100 x 140 cm	5714882010297
300-302-V-220_KK	Incontinence Cover, size 140 x 220 cm	5714882010341
300-302-V-KK	Incontinence Cover, size 140 x 200 cm	5714882010327
300-304-V-220-KK	Incontinence Cover, w/mesh, size 140 x 220 cm	5714882010402
300-304-V-KK	Incontinence Cover, w/mesh, size 140 x 200 cm	5714882010389

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac KneedMe [®] To Go
Type / Model:	See TD 2.1
Class:	Class 1 – according to regulation (EU) 2017/745

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 07.05.21

Pia Christiansen

Pia Christiansen
Managing Director

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Protac KneedMe® To Go

Nummer	Beskrivelse	UDI
700-755-U-3820-30	Protac KneedMe To Go, Aqua	5714882013038
700-755-U-3820-40	Protac KneedMe To Go, Lime	5714882013052
700-755-U-3820-80	Protac KneedMe To Go, Dark Grey	5714882013076
700-755-B-3820-80_KK	Protac KneedMe To Go	5714882013021
700-755-U-3820-30_KK	Protac KneedMe To Go, Aqua	5714882013045
700-755-U-3820-40_KK	Protac KneedMe To Go, Lime	5714882013069
700-755-U-3820-80_KK	Protac KneedMe To Go, Dark Grey	5714882013083

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac KneedMe[®]
Type / Model:	See TD 2.1 page 1
Class:	Class 1 – according to regulation (EU) 2017/745 – Rule 4.1-1

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

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EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 29.04.21



Pia Christiansen
Managing Director

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Protac KneedMe®

Number	Description	UDI
700-751-3820-30	Protac KneedMe®, Aqua	5714882012956
700-751-3820-40	Protac KneedMe®, Lime	5714882012970
700-751-3820-41	Protac KneedMe®, Støvet Grøn	5714882012994

Variants

700-751-3820-30_KK	Protac KneedMe®, Aqua, KK	5714882012963
700-751-3820-40_KK	Protac KneedMe®, Lime, KK	5714882012987
700-751-3820-41_KK	Protac KneedMe®, Støvet Grøn, KK	5714882013007

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac MyBaSe [®]
Type / Model:	700-720-10
Class:	Class 1 – according to regulation (EU) 2017/745

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 07.05.21



Pia Christiansen
Managing Director

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac MyFit [®]
Type / Model:	See TD 2.1 page 1 – 3
Class:	Class 1 – according to regulation (EU) 2017/745

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 13.04.2021



Pia Christiansen
Managing Director

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Protac MyFit®

Number	Description	UDI.
800-821-10-3XL/4XL	Protac MyFit, size. 3XL/4XL	5714882013670
800-821-10-5XL/6XL	Protac MyFit, size. 5XL/6XL	5714882013694
800-821-10-B	Protac MyFit, size B	5714882013533
800-821-10-J	Protac MyFit, size J	5714882013557
800-821-10-M/L	Protac MyFit, size M/L	5714882013571
800-821-10-S	Protac MyFit, size S	5714882013595
800-821-10-S_KK	Protac MyFit, size XL/2XL	5714882013601
800-821-10-XL/2XL	Protac MyFit, size XL/2XL	5714882013618
800-821-10-XS	Protac MyFit, size XS	5714882013632
800-821-10-XXS	Protac MyFit, size XXS	5714882013656

Variants

800-821-10-3XL/4XL_K	Protac MyFit, size.3XL/4XL,	5714882013687
800-821-10-5XL/6XL_K	Protac MyFit, size. 5XL/6XL	5714882013700
800-821-10-B_KK	Protac MyFit, size B	5714882013540
800-821-10-J_KK	Protac MyFit, size J	5714882013564
800-821-10-M/L_KK	Protac MyFit, size M/L	5714882013588
800-821-10-S_KK	Protac MyFit, size S	5714882013601
800-821-10-XL/2XL_KK	Protac MyFit, size XS/2XL	5714882013625
800-821-10-XS_KK	Protac MyFit, size XS	5714882013649
800-821-10-XXS_KK	Protac MyFit, size XXS	5714882013854

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Protac MyFit®

Number	Description	UDI
800-841-10-3XL/4XL	Protac MyFit, size 3XL/4XL	5714882013854
800-841-10-5XL/6XL	Protac MyFit, size 5XL/6XL	5714882013878
800-841-10-B	Protac MyFit, size B	5714882013717
800-841-10-J	Protac MyFit, size J	5714882013731
800-841-10-M/L	Protac MyFit, size M/L	5714882013755
800-841-10-S	Protac MyFit, size S	5714882013779
800-841-10-XL/2XL	Protac MyFit, size XL/2XL	5714882013793
800-841-10-XS	Protac MyFit, size XS	5714882013816
800-841-10-XXS	Protac MyFit, size XXS	5714882013830

Variants

800-841-10-3XL/4XL_K	Protac MyFit, size 3XL/4XL	5714882013861
800-841-10-5XL/6XL_K	Protac MyFit, size 5XL/6XL	5714882013885
800-841-10-B_KK	Protac MyFit, size B	5714882013724
800-841-10-J_KK	Protac MyFit, size J	5714882013748
800-841-10-M/L_KK	Protac MyFit, size M/L	5714882013762
800-841-10-S_KK	Protac MyFit, size S	5714882013786
800-841-10-XL/2XL_KK	Protac MyFit, size XL/2XL	5714882013809
800-841-10-XS_KK	Protac MyFit, size XS	5714882013823
800-841-10-XXS_KK	Protac MyFit, size XXS	5714882013847

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Protac MyFit®

Number	Description	UDI
800-850-10-M/L	Protac MyFit, size M/L,	5714882013892
800-850-10-S	Protac MyFit, size S	5714882013915
800-850-10-XL/2XL	Protac MyFit, size XL/2XL	5714882013939
800-850-10-XS	Protac MyFit, size XS	5714882013953
800-850-10-XXS	Protac MyFit, size XXS	5714882013977

Variants

800-850-10-M/L_KK	Protac MyFit, size M/L,	5714882013908
800-850-10-S_KK	Protac MyFit, size S	5714882013922
800-850-10-XL/2XL_KK	Protac MyFit, size XL/2XL	5714882013946
800-850-10-XS_KK	Protac MyFit, size XS	5714882013960
800-850-10-XXS_KK	Protac MyFit, size XXS	5714882013984

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac SenSit® Nature Puff
Type / Model:	600-610-3000-35
Class:	Class 1 – according to regulation (EU) 2017/745 – Rule 4.1-1

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 07.05.21



Pia Christiansen
Managing Director

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac SenSit [®] Nature
Type / Model:	See TD 2.1
Class:	Class 1 – according to regulation (EU) 2017/745 – Rule 4.1-1

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 07.05.21



Pia Christiansen
Managing Director

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Protac SenSit® Nature

Number	Description	UDI
600-602-3000-35	Protac SenSit Nature	5714882030547
600-702-3000-35	Protac SenSit Nature	5714882030820

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac SenSit[®] Puff
Type / Model:	See TD 2.1 page 1
Class:	Class 1 – according to regulation (EU) 2017/745 – Rule 4.1-1

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 07.05.21



Pia Christiansen
Managing Director

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Protac SenSit® Puff

Number	Description	UDI
600-610-3800-24	Protac SenSit Puff, Rust Rød	5714882011577
600-610-3820-02	Protac SenSit Puff, Offwhite	5714882011591
600-610-3820-10	Protac SenSit Puff, Sort	5714882011607
600-610-3820-20	Protac SenSit Puff, Rød	5714882011614
600-610-3820-30	Protac SenSit Puff, Aqua	5714882011621
600-610-3820-40	Protac SenSit Puff, Lime	5714882011638
600-610-3820-41	Protac SenSit Puff, Støvet Grøn	5714882011645
600-610-3820-80	Protac SenSit Puff, Mørke Grå	5714882011652

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac SenSit[®] Straight
Type / Model:	See TD 2.1 page 1
Class:	Class 1 – according to regulation (EU) 2017/745 – Rule 4.1-1

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 29.04.21



Pia Christiansen
Managing Director

Dok. Nr.: TD 2.1	Emne: Declaration of Conformity - Appendix	Version: 1	Dato: 29.04.21	Opdateret
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Protac SenSit® Straight

Number	Description	UDI
600-651-3820-30	Protac SenSit® Straight, Aqua	5714882011669
600-651-3820-40	Protac SenSit® Straight, Lime	5714882011676
600-651-3820-41	Protac SenSit® Straight, Dusty Green	5714882011683
600-651-3820-80	Protac SenSit® Straight, Dark Grey	5714882011690

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac SenSit[®]
Type / Model:	See TD 2.1 page 1
Class:	Class 1 – according to regulation (EU) 2017/745 – Rule 4.1-1

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 23.02.21



Pia Christiansen
Managing Director

Dok. Nr.: TD 2.1	Emne: Declaration of Conformity - Appendix	Version: 2	Dato: 18.03.2020	Opdateret 07.10.2020
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Protac SenSit®

Number	Description	UDI
600-601-3800-24	Protac SenSit® Rusty Red	5714882011485
600-602-3820-02	Protac SenSit® Off White	5714882011508
600-602-3820-10	Protac SenSit® Black	5714882011515
600-602-3820-20	Protac SenSit® Red	5714882011522
600-602-3820-30	Protac SenSit® Aqua	5714882011539
600-602-3820-40	Protac SenSit® Lime	5714882011546
600-602-3820-41	Protac SenSit® Dusty Green	5714882011553
600-602-3820-80	Protac SenSit® Dark Grey	5714882011560
600-701-3800-24	Protac SenSit® Rusty Red	5714882012567
600-702-3820-02	Protac SenSit® Off White	5714882011737
600-702-3820-10	Protac SenSit® Black	5714882011744
600-702-3820-20	Protac SenSit® Red	5714882011751
600-702-3820-30	Protac SenSit® Aqua	5714882011768
600-702-3820-40	Protac SenSit® Lime	5714882011775
600-702-3820-41	Protac SenSit® Dusty Green	5714882011782
600-702-3820-80	Protac SenSit® Dark Grey	5714882011799

Declaration of Conformity

Manufacturer:	Protac A/S
Address:	Niels Bohrs Vej 31D, DK8660 Skanderborg, Denmark
SRN:	DK-MF-000000963

Product name:	Protac SensOn [®]
Type / Model:	See TD 2.1
Class:	Class 1 – according to regulation (EU) 2017/745

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 07.05.21



Pia Christiansen
Managing Director

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Protac SensOn®

Nummer	Beskrivelse	UDI
800-100-10-J	Protac SensOn, Black str.J	5714882030806
800-100-10-J_KK	Protac SensOn, Black str. J	5714882030813
800-100-10-M/L	Protac SensOn, Black str. M/L	5714882013335
800-100-10-M/L_KK	Protac SensOn, Black str. M/L	5714882013342
800-100-10-XS/S	Protac SensOn, Black str.XS/S	5714882013359
800-100-10-XS/S_KK	Protac SensOn, Black str.XS/S	5714882013366
800-100-10-XXS	Protac SensOn, Black str.XXS	5714882013373
800-100-10-XXS_KK	Protac SensOn, Black str.XXS	5714882013380