

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
Udført af: BSO	Godkendt af: PC			Side: 1-4

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

Dok. Nr.: TD 2.1	Emne: Declaration of Conformity - Appendix	Version: 2	Dato: 18.03.2020	Opdateret 07.10.2020
Udført af: BSO	Godkendt af: PC			Side: 2-4

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

Dok. Nr.: TD 2.1	Emne: Declaration of Conformity - Appendix	Version: 2	Dato: 18.03.2020	Opdateret 07.10.2020
Udført af: BSO	Godkendt af: PC			Side: 3-4

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

Dok. Nr.: TD 2.1	Emne: Declaration of Conformity - Appendix	Version: 2	Dato: 18.03.2020	Opdateret 07.10.2020
Udført af: BSO	Godkendt af: PC			Side: 4-4

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