

Declaration of Conformity

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

Produkt Name:	Protac Ball Cushion [®]
Basic UDI-DI:	57148822009N
EMDN code:	Y99
Model:	See appendix TD 2.1-page 1-2
Intended use:	The cushion is used to stimulate the different senses in children and adults. The various sensory stimuli can be influenced via applying weight and pressure to the tactile sense (the sense of touch) in the skin and the proprioceptive sense (the sense of movement) in muscles and joints.
Class:	Class 1 – Rule 1 Annex I – II - III

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

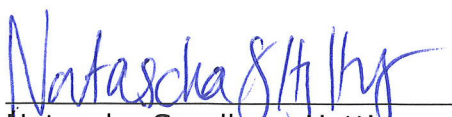
European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016/A11:2021 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices

DS/EN ISO 21856:2022: Medical devices - Assistive products - General requirements and test methods.


Natascha Sandberg-Hytting
Managing Director

Skanderborg d. 19.09.22

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Protac Ball Cushion®

Number	Description	UDI-DI
200-201-10-30	Protac Ball Cushion®, Aqua, 40x40 cm	5714882007686
200-201-10-40	Protac Ball Cushion®, Lime, 40x40 cm*	5714882007709
200-201-10-80	Protac Ball Cushion®, Dark Grå, 40x40 cm	5714882007822
200-201-10-4-30	Protac Ball Cushion®, Aqua, 40x40 cm, 4 sections	5714882007747
200-201-10-4-80	Protac Ball Cushion®, Dark Grey, 40x40 cm, 4 sections	5714882007808
200-201-11-80	Protac Ball Cushion®, Dark Grey,	5714882007853
200-201-11-L-80	Protac Ball Cushion®, Dark Grey, L,	5714882007846
200-201-12-80	Protac Ball Cushion®, Dark Grey, 30x35 cm	5714882007860
200-201-13-80	Protac Ball Cushion®, Dark Grey, 30x30 cm	5714882007884
200-201-14-80	Protac Ball Cushion®, Dark Grey, 35x35 cm	5714882007891
200-201-15-30	Protac Ball Cushion®, Aqua, 40x40 cm	5714882007907
200-201-15-80	Protac Ball Cushion®, Dark Grey, 40x40 cm	5714882007969
200-202-10-30	Protac Ball Cushion®, Aqua, 40x40 cm	5714882007983
200-202-10-80	Protac Ball Cushion®, Dark Grey, 40x40 cm.	5714882008126
200-202-10-4-30	Protac Ball Cushion®, Aqua, 40x40 cm, 4 sections	5714882008041
200-202-10-4-80	Protac Ball Cushion®, Dark Grey, 40x40 cm. 4 sections	5714882008102
200-202-11-80	Protac Ball Cushion®, Dark Grey, Highchair	5714882008140
200-202-12-80	Protac Ball Cushion®, Dark Grey, 30x35 cm	5714882008157
200-202-13-80	Protac Ball Cushion®, Dark Grey, 30x30 cm.	5714882008171
200-202-14-80	Protac Ball Cushion®, Dark Grey, 35x35 cm	5714882008188
200-202-15-30	Protac Ball Cushion®, Aqua, 40x40 cm	5714882008195
200-202-15-80	Protac Ball Cushion®, Dark Grey, 40x40 cm	5714882008256

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Protac Ball Cushion®

Number	Description	UDI-DI
200-201-10-30_KK	Protac Ball Cushion®, Aqua, 40x40 cm	5714882007693
200-201-10-40_KK	Protac Ball Cushion®, Lime, 40x40 cm	5714882007716
200-201-10-41_KK	Protac Ball Cushion®, Dusty Green, 40x40 cm	5714882007730
200-201-10-80_KK	Protac Ball Cushion®, Dark Grey, 40x40 cm	5714882007839
200-201-10-4-30_KK	Protac Ball Cushion®, Aqua, 40x40 cm, 4 sections	5714882007754
200-201-10-4-40_KK	Protac Ball Cushion®, Lime, 40x40 cm, 4 sections	5714882007778
200-201-10-4-41_KK	Protac Ball Cushion®, Dusty Green 40x40cm, 4 sections	5714882007792
200-201-10-4-80_KK	Protac Ball Cushion®, Dark Grey, 40x40 cm, 4 sections	5714882007815
200-201-12-80_KK	Protac Ball Cushion®, Dark Grey 30x35 cm	5714882007877
200-201-15-30_KK	Protac Ball Cushion®, Aqua, 40x40 cm	5714882007914
200-201-15-40_KK	Protac Ball Cushion®, Lime, 40x40 cm	5714882007938
200-201-15-41_KK	Protac Ball Cushion®, Dusty Green, 40x40 cm	5714882007952
200-201-15-80_KK	Protac Ball Cushion®, Dark Grey, 40x40 cm	5714882007976
200-202-10-80_KK	Protac Ball Cushion®, Dark Grey, 40x40 cm	5714882008133
200-202-10-4-30_KK	Protac Ball Cushion®, Aqua, 40x40 cm, 4 sections	5714882008058
200-202-10-4-80_KK	Protac Ball Cushion®, Aqua, 40x40 cm, 4 sections	5714882008119
200-202-12-80_KK	Protac Ball Cushion®, Dark Grey 30x35 cm	5714882008164
200-202-15-30_KK	Protac Ball Cushion®, Aqua, 40x40 cm	5714882008201
200-202-15-80_KK	Protac Ball Cushion®, Dark Grey, 40x40 cm	5714882008263