

Declaration of Conformity

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

Produkt Name:	Protac SenSit®
Basic UDI-DI:	5714882600AA
EMDN code:	Y99
Model:	See appendix TD 2.1-page 1
Intended use:	The chair and puff are 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:

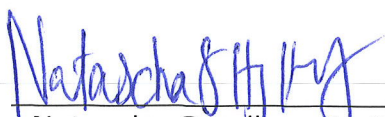
European Medical Device Regulation (EU) 2017/745

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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Made by: BSO				Page: 1-1

Protac SenSit®

Number	Description	UDI-DI
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
600-702-3820-02	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

Protac SenSit® Set

600-611-3800-24	Protac SenSit® + Puff Rusty Red	5714882031537
600-612-3820-02	Protac SenSit® + Puff Off White	5714882031551
600-612-3820-10	Protac SenSit® + Puff Black	5714882031568
600-612-3820-20	Protac SenSit® + Puff Red	5714882031575
600-612-3820-30	Protac SenSit® + Puff Aqua	5714882031582
600-612-3820-40	Protac SenSit® + Puff Lime	5714882031599
600-612-3820-41	Protac SenSit® + Puff Dusty Green	5714882031605
600-612-3820-80	Protac SenSit® + Puff Dark Grey	5714882031612
600-712-3820-02	Protac SenSit® + Puff Off White	5714882011737
600-712-3820-10	Protac SenSit® + Puff Black	5714882011744
600-712-3820-20	Protac SenSit® + Puff Red	5714882011751
600-712-3820-30	Protac SenSit® + Puff Aqua	5714882011768
600-712-3820-40	Protac SenSit® + Puff Lime	5714882011775
600-712-3820-41	Protac SenSit® + Puff Dusty Green	5714882011782
600-712-3820-80	Protac SenSit® + Puff Dark Grey	5714882011799