

Declaration of Conformity

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

Produkt Name:	Protac SenSit® Straight
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:

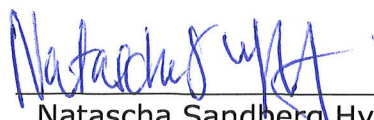
European Medical Device Regulation (EU) 2017/745

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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Protac SenSit® Straight

Number	Description	UDI-DI
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

Protac SenSit® Straight Set

Number	Description	UDI-DI
600-661-3820-30	Protac SenSit® Straight + Puff, Aqua	5714882031698
600-661-3820-40	Protac SenSit® Straight + Puff, Lime	5714882031704
600-661-3820-41	Protac SenSit® Straight + Puff, Dusty Green	5714882031711