PROTAC®
INTEGRATING SENSES

Declaration of Conformity

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

Produkt Name:	Protac SenSack®
Basic UDI-DI:	57148821009H
EMDN code:	Y99
Model:	See appendix TD 2.1-page 1-2
Intended use:	The sleeping bag 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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TD 2.1	Declaration of Conformity - Appendix	1	08.02.22	
Made by: BSO	Approved by:			Page: 1-1

Protac SenSack®

Number	Description	UDI-DI
100-500-35-S	Protac SenSack® size S, ca. 4 kg	5714882031155
100-500-35-M	Protac SenSack® size M, ca. 5,5 kg	5714882031162
100-500-35-L	Protac SenSacK® size L, ca. 7,5 kg	5714882031179