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 KneedMe®
Basic UDI-DI:	571488270075FV
EMDN code:	Y99
Model:	See appendix TD 2.1-page 1
Intended use:	The knee blanket 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 KneedMe®

Number	Description	UDI-DI
700-751-3820-30	Protac KneedMe®, Aqua	5714882012956
700-751-3820-40	Protac KneedMe®, Lime	5714882012970
700-751-3820-41	Protac KneedMe®, Dusty Green	5714882012994
Variants		
700-751-3820-30_KK	Protac KneedMe®, Aqua, KK	5714882012963
700-751-3820-40_KK	Protac KneedMe®, Lime, KK	5714882012987
700-751-3820-41_KK	Protac KneedMe®, Dusty Green,KK	5714882013007