

Declaration of Conformity

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

Produkt Name:	Protac SensCircle®
Basic UDI-DI:	57148824009Y
EMDN code:	Y99
Model:	See appendix TD 2.1-page 1
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:

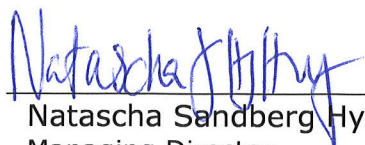
European Medical Device Regulation (EU) 2017/745

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 SensCircle®

Number	Description	UDI-DI
400-410-2600-38	Protac SensCircle®, Blue	5714882010563
400-410-2600-45	Protac SensCircle®, Green	5714882010570
400-410-3820-30	Protac SensCircle®, Aqua	5714882010587
400-410-3820-40	Protac SensCircle®, Lime	5714882010594
400-410-3820-80	Protac SensCircle®, Dark Grey	5714882010600
400-450-2600-38	Protac SensCircle®, Blue	5714882010617
400-450-2600-45	Protac SensCircle®, Green	5714882010624
400-450-3820-02	Protac SensCircle®, Off White	5714882010631
400-450-3820-30	Protac SensCircle®, Aqua	5714882010655
400-450-3820-40	Protac SensCircle®, Lime	5714882010679
400-450-3820-80	Protac SensCircle®, Dark Grey	5714882010693

Variants

400-450-3820-02_KK	Protac SensCircle®, Off White	5714882010648
400-450-3820-30_KK	Protac SensCircle®, Aqua	5714882010662
400-450-3820-40_KK	Protac SensCircle®, Lime	5714882010686
400-450-3820-80_KK	Protac SensCircle®, Dark Grey	5714882010709