

Declaration of Conformity

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

Produkt Name:	Protac SensOn®
Basic UDI-DI:	57148828001TH
EMDN code:	Y99
Model:	See appendix TD 2.1-page 1-2
Intended use:	The collar 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:

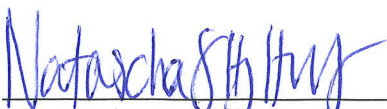
European Medical Device Regulation (EU) 2017/745

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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Made by: BSO	Approved: PC			Page: 1-1

Protac SensOn®

Number	Description	UDI-DI
800-110-10-J	Protac SensOn®, Black str.J	5714882031063
800-110-10-M/L	Protac SensOn®, Black str. M/L	5714882031087
800-110-10-S	Protac SensOn®, Black str.S	5714882031100
800-110-10-XS	Protac SensOn®, Black str.XS	5714882031124

Variants

Number	Description	UDI-DI
800-110-10-J_KK	Protac SensOn, Black str. J	5714882031070
800-110-10-M/L_KK	Protac SensOn, Black str. M/L	5714882031094
800-110-10-S_KK	Protac SensOn, Black str.S	5714882031117
800-110-10-XS_KK	Protac SensOn, Black str.XS	5714882031131