

Declaration of Conformity

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

Produkt Name:	Protac GroundMe®
Basic UDI-DI:	571488270071FM
EMDN code:	Y99
Model:	See appendix TD 2.1-page 1
Intended use:	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:

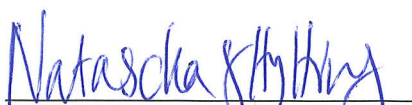
European Medical Device Regulation (EU) 2017/745

Harmonized standards:

EN ISO 13485:2016 Medical Devices – Quality management systems – Requirements for regulatory purposes.

EN ISO 14971:2019 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 19.09.22

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Protac GroundMe®

Number	Description	UDI-DI
700-710-10-3820-30	Protac GroundMe®, 10 cm, Aqua	5714882012789
700-710-10-3820-40	Protac GroundMe®, 10 cm, Lime	5714882012802
700-710-10-3820-41	Protac GroundMe®, 10 cm, Dusty Green	5714882012826
700-710-10-3820-80	Protac GroundMe®, 10 cm, Dark Grey	5714882012840
700-710-20-3820-30	Protac GroundMe®, 20 cm, Aqua	5714882012864
700-710-20-3820-40	Protac GroundMe®, 20 cm, Lime	5714882012888
700-710-20-3820-41	Protac GroundMe®, 20 cm, Dusty Green	5714882012901
700-710-20-3820-80	Protac GroundMe®, 20 cm, Dark Grey	5714882012925