

Declaration of Conformity

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

Produkt Name:	Protac MyFit®
Basic UDI-DI:	57148828008TX
EMDN code:	Y99
Model:	See appendix TD 2.1-page 1-3
Intended use:	The vest 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:

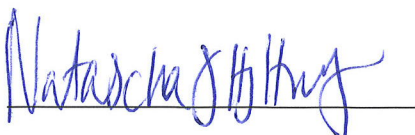
European Medical Device Regulation (EU) 2017/745

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	Godkendt af: PC			Side: 1-3

Protac MyFit®

Number	Description	UDI-DI
800-821-10-3XL/4XL	Protac MyFit, size. 3XL/4XL	5714882013670
800-821-10-5XL/6XL	Protac MyFit, size. 5XL/6XL	5714882013694
800-821-10-B	Protac MyFit, size B	5714882013533
800-821-10-J	Protac MyFit, size J	5714882013557
800-821-10-M/L	Protac MyFit, size M/L	5714882013571
800-821-10-S	Protac MyFit, size S	5714882013595
800-821-10-S_KK	Protac MyFit, size XL/2XL	5714882013601
800-821-10-XL/2XL	Protac MyFit, size XL/2XL	5714882013618
800-821-10-XS	Protac MyFit, size XS	5714882013632
800-821-10-XXS	Protac MyFit, size XXS	5714882013656

Variants

800-821-10-3XL/4XL_K	Protac MyFit, size.3XL/4XL,	5714882013687
800-821-10-5XL/6XL_K	Protac MyFit, size. 5XL/6XL	5714882013700
800-821-10-B_KK	Protac MyFit, size B	5714882013540
800-821-10-J_KK	Protac MyFit, size J	5714882013564
800-821-10-M/L_KK	Protac MyFit, size M/L	5714882013588
800-821-10-S_KK	Protac MyFit, size S	5714882013601
800-821-10-XL/2XL_KK	Protac MyFit, size XS/2XL	5714882013625
800-821-10-XS_KK	Protac MyFit, size XS	5714882013649
800-821-10-XXS_KK	Protac MyFit, size XXS	5714882013854

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Protac MyFit®

Number	Description	UDI-DI
800-841-10-3XL/4XL	Protac MyFit, size 3XL/4XL	5714882013854
800-841-10-5XL/6XL	Protac MyFit, size 5XL/6XL	5714882013878
800-841-10-B	Protac MyFit, size B	5714882013717
800-841-10-J	Protac MyFit, size J	5714882013731
800-841-10-M/L	Protac MyFit, size M/L	5714882013755
800-841-10-S	Protac MyFit, size S	5714882013779
800-841-10-XL/2XL	Protac MyFit, size XL/2XL	5714882013793
800-841-10-XS	Protac MyFit, size XS	5714882013816
800-841-10-XXS	Protac MyFit, size XXS	5714882013830

Variants

800-841-10-3XL/4XL_K	Protac MyFit, size 3XL/4XL	5714882013861
800-841-10-5XL/6XL_K	Protac MyFit, size 5XL/6XL	5714882013885
800-841-10-B_KK	Protac MyFit, size B	5714882013724
800-841-10-J_KK	Protac MyFit, size J	5714882013748
800-841-10-M/L_KK	Protac MyFit, size M/L	5714882013762
800-841-10-S_KK	Protac MyFit, size S	5714882013786
800-841-10-XL/2XL_KK	Protac MyFit, size XL/2XL	5714882013809
800-841-10-XS_KK	Protac MyFit, size XS	5714882013823
800-841-10-XXS_KK	Protac MyFit, size XXS	5714882013847

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Protac MyFit®

Number	Description	UDI-DI
800-850-10-M/L	Protac MyFit, size M/L,	5714882013892
800-850-10-S	Protac MyFit, size S	5714882013915
800-850-10-XL/2XL	Protac MyFit, size XL/2XL	5714882013939
800-850-10-XS	Protac MyFit, size XS	5714882013953
800-850-10-XXS	Protac MyFit, size XXS	5714882013977

Variants

800-850-10-M/L_KK	Protac MyFit, size M/L,	5714882013908
800-850-10-S_KK	Protac MyFit, size S	5714882013922
800-850-10-XL/2XL_KK	Protac MyFit, size XL/2XL	5714882013946
800-850-10-XS_KK	Protac MyFit, size XS	5714882013960
800-850-10-XXS_KK	Protac MyFit, size XXS	5714882013984