

# Declaration of Conformity

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

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|----------------------|--|
| <b>Produkt Name:</b> | Protac SenSit® Nature  |
| <b>Basic UDI-DI:</b> | 5714882600AA   |
| <b>EMDN code:</b>    | Y99  |
| <b>Model:</b>        | See appendix TD 2.1-page 1   |
| <b>Intended use:</b> | The chair 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. |
| <b>Class:</b>        | Class 1 – Rule 1 Annex I – II - III  |

We hereby declare that the above-mentioned products comply with the following regulation and harmonized standards:

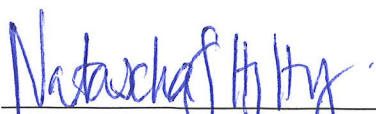
## European Medical Device Regulation (EU) 2017/745

### 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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| <b>Doc. No.:</b><br>TD 2.1 | <b>Subject:</b><br>Declaration of Conformity - Appendix | <b>Version:</b><br>2 | <b>Date:</b><br>15.06.20 | <b>Revised:</b><br>01.06.22 |
| <b>Made by:</b><br>BSO     |   |                      |                          | <b>Page:</b><br>1-1         |

## Protac SenSit® Nature

| Number          | Description               | UGI-DI        |
|-----------------|---------------------------|---------------|
| 600-602-3000-35 | Protac SenSit® Nature     | 5714882030547 |
| 600-612-3000-35 | Protac SenSit® Nature set | 5714882031544 |

## Accessory

|                 |                            |               |
|-----------------|----------------------------|---------------|
| 600-610-3000-35 | Protac SenSit® Nature Puff | 5714882030578 |
|-----------------|----------------------------|---------------|