

# Declaration of Conformity

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

|                      |                                                              |
|----------------------|--------------------------------------------------------------|
| <b>Product name:</b> | <b>Protac SenSit®</b>                                        |
| <b>Type / Model:</b> | See TD 2.1 page 1                                            |
| <b>Class:</b>        | Class 1 – according to regulation (EU) 2017/745 – Rule 4.1-1 |

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

EN ISO 12182:2012 Medical devices - Assistive products for persons with disability- General requirements and test methods.

Skanderborg 23.02.21



Pia Christiansen  
Managing Director

|                            |                                                      |                      |                            |                                |
|----------------------------|------------------------------------------------------|----------------------|----------------------------|--------------------------------|
| <b>Dok. Nr.:</b><br>TD 2.1 | <b>Emne:</b><br>Declaration of Conformity - Appendix | <b>Version:</b><br>2 | <b>Dato:</b><br>18.03.2020 | <b>Opdateret</b><br>07.10.2020 |
| <b>Udført af:</b><br>BSO   |                                                      |                      |                            | <b>Side:</b><br>1-1            |

## Protac SenSit®

| Number          | Description                | UDI           |
|-----------------|----------------------------|---------------|
| 600-601-3800-24 | Protac SenSit® Rusty Red   | 5714882011485 |
| 600-602-3820-02 | Protac SenSit® Off White   | 5714882011508 |
| 600-602-3820-10 | Protac SenSit® Black       | 5714882011515 |
| 600-602-3820-20 | Protac SenSit® Red         | 5714882011522 |
| 600-602-3820-30 | Protac SenSit® Aqua        | 5714882011539 |
| 600-602-3820-40 | Protac SenSit® Lime        | 5714882011546 |
| 600-602-3820-41 | Protac SenSit® Dusty Green | 5714882011553 |
| 600-602-3820-80 | Protac SenSit® Dark Grey   | 5714882011560 |
| 600-701-3800-24 | Protac SenSit® Rusty Red   | 5714882012567 |
| 600-702-3820-02 | Protac SenSit® Off White   | 5714882011737 |
| 600-702-3820-10 | Protac SenSit® Black       | 5714882011744 |
| 600-702-3820-20 | Protac SenSit® Red         | 5714882011751 |
| 600-702-3820-30 | Protac SenSit® Aqua        | 5714882011768 |
| 600-702-3820-40 | Protac SenSit® Lime        | 5714882011775 |
| 600-702-3820-41 | Protac SenSit® Dusty Green | 5714882011782 |
| 600-702-3820-80 | Protac SenSit® Dark Grey   | 5714882011799 |