CE

EU DECLARATION OF CONFORMITY

Manufacturer: **PROSTAF Sp. z o.o. Sp.k.**
ul. Jasielska 7a
60-476 Poznań
Poland
SRN: **PL-MF-000002123**
Basic UDI-DI: **590828079oprawkiQ2**

Products: **Optical frames**

Name of products: **BERGMAN**
NORDIK by BERGMAN
CHILI by BERGMAN
ORANGE by BERGMAN
BALTICA

Classification: Medical device – Class I (rule l) in accordance with Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

We declare the compliance of the above medical device with the relevant provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 and following standards:

- **EN ISO 20417:2021**
- **EN ISO 15223-1:2016**
- **EN ISO 14971:2019**
- **EN ISO 12870:2018**
- **EN ISO 8624:2020**
- **EN ISO 13485:2016/AC:2018**
- **EN ISO 10993-1:2021-06**

Applied conformity assessment procedure for optical frames:
In accordance with Annex IV of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

PROSTAF
Spółka z ograniczoną odpowiedzialnością
Spółka komandytowa
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Izabela Żwawiak
Proxy

Poznań, May 24th, 2023

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PROSTAF