



EU DECLARATION OF CONFORMITY

Manufacturer: **BLUE IRIS Sp. z o.o. Sp.k.**
ul. Jana Rymarkiewicza 5a
60-681 Poznań
Poland

SRN: **PL-MF-000002122**
Basic UDI-DI: **590383900okularyH5**

Products: **Reading glasses**

Name of products: **BRILO
CORRECT+**

Individual sizes of the models are presented in Section 1 of Technical Documentation of the product TF-01 Reading glasses.

Classification: Medical device – Class I (rule I) 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
- EN ISO 15223-1
- EN ISO 14971
- EN ISO 12870
- EN ISO 13485
- EN ISO 10993-1
- EN 62366-1
- EN ISO 8624
- EN 14139
- EN ISO 8980-5
- EN ISO 14889

Applied conformity assessment procedure for reading glasses:

In accordance with Annex IV of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

BLUE IRIS
Spółka z ograniczoną odpowiedzialnością
Spółka komandytowa
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Izabela Żwawiak
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