# EU Declaration of Conformity

CE

| Class I medical device | | | |
|---|---|---|---|
| Type: | Frames for prescription glasses | | |
| Model code: | P58 | | |
| Lot number: | see label - serial number | Date of manufacture: | see label - serial number |
| Basic UDI-DI: | 805930044P58GF | | |

| Manufacturer | |
|---|---|
| KUBORAUM | **KUBORAUM GMBH**<br>**Registered office:** via Dei Rizzi 1/I - 31010 - Maser (TV)<br>**VAT NO.**: 04703940264 |

**This declaration of conformity is issued under the sole responsibility of the manufacturer.**
**The product complies with laws and standards:**

- Regulation (EU) No. 2017/745 Medical Devices Regulation.
- UNI CEI EN ISO 15223-1:2021 Title: Medical devices - Symbols for use on medical device labels, labelling and information to be provided - Part 1: General requirements
- UNI CEI EN ISO 20417:2021 Medical devices - Information provided by the manufacturer
- UNI CEI EN 14971:2022 Application of risk management to medical devices
- Regulation (EU) 2023/988 on general product safety
- Directive 2001/95/EC “General Product Safety” (to be maintained for completeness until 13 December 2024)
- UNI EN ISO 12870:2018 Ophthalmic optics - Spectacle frames - Requirements and test methods
- Ministerial Decree of 23 July 1998 Provisions relating to the trade in spectacles in implementation of Article 20 of Legislative Decree No 46 of 1997
- UNI EN ISO 11381:2017 Ophthalmic optics - Spectacle frames - Screw threading
- UNI EN ISO 8624:2021 Ophthalmic optics - Spectacle frames - Measuring system and terminology
- UNI EN ISO 7998:2006 Ophthalmic optics - Spectacle frames - Lists of equivalent terms and vocabulary)

The manufacturer undertakes to transmit, in response to a duly substantiated request by the national authorities, relevant product information.

Signed for and on behalf of:

| Surname and First Name | Role | Date |
|---|---|---|
| Sergio Eusebi | Legal representative | 06/12/2024 |

**Signature:** _____


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| MarcaturaCE.net<br>**Company ISO 9001 certified** | **CEC.group S.r.l.** - Via Lauro, 95 - 35010 - Cadoneghe (PD) - Italy<br>**Consultants and Experts** for: **Italian Tax Police, Customs Authorities, Carabinieri, State Police, Unioncamere, Courts.** |
| **Advice on the design of the technical dossier template was provided by CEC.group S.r.l.** | |