EU Declaration of Conformity

CE

Class I medical device			
Type:	Frames for prescription glasses		
Model code:	H61		
Lot number:	see label - serial number	Date of manufacture:	see label - serial number
Basic UDI-DI:	805259576H61KA		

Manufacturer	
KUBORAUM	**KUBORAUM GMBH** **Registered office:** via Dei Rizzi 1/I - 31010 - Maser (TV) **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	05/12/2024

Signature: _____

MarcaturaCE.net

Company ISO 9001 certified

CEC.group S.r.l. - Via Lauro, 95 - 35010 - Cadoneghe (PD) - Italy
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.