EU DECLARATION OF CONFORMITY (EN) F-52.1. - REV:06 – 03/17/2026

We **Walter Binde GmbH & Co. KG** **Königstraße 134b** **D-32427 Minden**	*Declarations of conformity for* *Spectacle frames*

declare under sole responsibility that The medical device is a spectacle frame without corrective lenses (Class 1).

ECRI code (UMDNS) 11-667 / GMDN code 32816

European Medical Device Nomenclature (EMDN) - Q02100201 - METAL FRAMES WITHOUT LENSES; Q02100202 - PLASTIC FRAMES WITHOUT LENSES; Q02100203 - METAL AND PLASTIC FRAMES WITHOUT LENSES

MDR Code: MDN 1206 Non-active non-implantable ophthalmological products.

CND Code according to Medical Device Regulation EU 2017/745:

MDT 2001 Products manufactured using metalworking processes.

MDT 2002 Products manufactured using plastic processing methods

complies with the requirements of Regulation (EU) 2017/745 on medical devices (MDR).

Intended purpose:	**Name: Corrective frame (short: eyeglass frame)** **Eyeglass frames are to be classified as non-invasive products with long-term contact with the human body surface within the meaning of Regulation (EU) 2017/754 Annex VIII.** **Intended use: mechanical fixation of corrective lenses in front of the eyes on the patient's head.**
Classification rules:	**Classification according to Regulation (EU) 2017/754: Class I Annex VIII (Classification rules: Chapter 1. Duration of use 1.3 / Chapter 3. Non-invasive products 4.1) Conformity assessment procedures according to Annexes IX to XI. Assignment of the basic UDI-DI according to MDCG 2025-8**
Applied harmonized standards *(Excerpt of the main standards):*	**EN ISO 13485: 2021-12 Medical devices - Quality management systems - Requirements for regulatory purposes** **DIN EN 62366-1:2021-08 Medical devices - Part 1: Application of usability to medical devices** **EN ISO 15223-1:2022-02 Medical devices - Symbols to be used on medical devices, marking and information to be supplied - Part 1: General requirements** **EN ISO 14971:2022-04 Medical devices - Application of risk management to medical devices** **ISO/TR 24971:2022-03 Medical devices – Guidance on the application of ISO 14971** **DIN EN ISO 10993-1:2021-05 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system** **DIN EN ISO 10993-5:2009-10 Biological evaluation of medical devices - Part 5: In vitro cytotoxicity tests** **DIN EN ISO 10993-10:2023-04 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization** **DIN EN ISO 10993-18:2021-03 Biological evaluation of medical devices - Part 18: Chemical characterization of materials for medical devices within the framework of a risk management system** **DIN EN ISO 12870:2026-01 Optometry - Spectacle frames - Requirements and test methods** **DIN EN 16128:2026-01 Ophthalmic optics - Reference method for determining the nickel release of spectacle frames and sunglasses** **DIN EN ISO 12312-1:2023-7 Eye and face protection - Sunglasses and similar eye protection - Part 1: Sunglasses for general use** **DIN EN ISO 7998:2006-01 Optometry - Spectacle frames - List of equivalent terms and vocabulary**
Other normative documents:	**EC Regulation No. 2020/2096 REACH & 1907/2006 REACH on the Registration, Evaluation, Authorisation and Restriction of Chemicals**
Technical documentation & specifications:	**The relevant documents are documented and stored at the company Binde-Optik.**
Registration and BASE UDI-DI	**Registration authority: District government of Detmold/NRW/Germany (DE/CA19)** **Registration number from 27.05.1998 to 25.05.2021 (DE/CA 19-24.40-01-(245)- 1)** **Registration number from 26.05.2021 (SRN: DE-MF-000006258)** **Assignment of the base UDI-DI according to MDCG 2025-8 with the following divisions:** **4066398F-MET-FUL-9R (Q02100201) Full Rim - Metal** **4066398F-PLA-FUL-7J (Q02100202) Full Rim - Plastic** **4066398F-MIX-FUL-DH (Q02100203) Full Rim – Metal & Plastic** **4066398F-MET-HAF-6H (Q02100201) Nylon - Metal** **4066398F-MIX-HAF-A9 (Q02100203) Nylon – Metal & Plastic** **4066398F-MET-RL-WG (Q02100201) Rimless - Metal** **4066398F-MIX-RL-ZG (Q02100203) Rimless – Metal & Plastic**
Anlagen	**Model lists containing all spectacle frames to which this declaration of conformity applies are listed in Annex F-52.2, Declarations of Conformity – Model List. Subdivisions according to BASE UDI are shown in the F-38 Annex product groups spectacle frames are listed and can be requested from Binde-Optik.**

Minden, March 17, 2026 place, date	Jörn Binde . . . . . . **Jörn Binde / CEO & Managing Director**