

EU DECLARATION OF CONFORMITY
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF
THE COUNCIL. of 5 April 2017 on MEDICAL DEVICES,



MANUFACTURER <i>(Name / Brand or commercial name of the manufacturer / complete legal address)</i>	Chongqing Muzikoptical Co.,ltd 1ST and 2nd floor,No.4 the capital of glasses, in the east of Yugong street,Rongchang Industrial Park Chongqing China Manufacture address:No.4 the capital of glasses, in the east of Yugong street,Rongchang Industrial Park Chongqing China
AUTHORIZED EUROPEAN REPRESENTATIVE <i>(Name and complete address)</i>	Kingsmead Service B.V. Zonnehof 36, 2632 BE, Nootdorp, Netherlands Email: office@kingsmead-service.com
SRN <i>(voluntary procurement in the first step of EUDAMED):</i>	NL-AR-000002066

DECLARE UNDER THEIR RESPONSIBILITY AS MANUFACTURER THAT THE PRODUCTS DESCRIBES BELOW MEET THE REQUIREMENTS OF THE REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICES

PRODUCT DESCRIPTION: CORRECTIVE SPECTACLE FRAMES

BRAND NAME:VIBE EYEWEAR

INTENDED USE:An ophthalmic device made of metal, acetate or plastic in order to include optical lenses manufactured in accordance with a standard prescription and used to correct the refractive errors of a patient's eyesight, e.g., refractive ametropia (myopia, hyperopia and astigmatism), and possibly to protect the eyes against radiation or mechanical hazards.

BASIC UDI-DI: 697460162001886PZ 697460162001887Q3 697460162001888Q5
 697460162001889Q7 697460162001890PQ

Classification (CLASS): class I (annex VIII regla 1) PRODUCTS ARE MARKED "CE"

Conformity statement according to Annex II and Annex III of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017.

Where applicable, name and identification number of the notified body, description of the conformity assessment procedure carried out and identification of the certificate or certificates issued.

Harmonized standards:

Generals

- EN ISO 14971: 2012. / EN ISO 15223-1:2016 / EN 1041:2008 + A1-2013 / EN ISO 10993-1:2009 +AC:2010 / EN 62366:2008 / ISO 13485:2016

The products are in conformity with the general obligation of security requested by 2001/95/CEE Directive and all its updates

Description of product: OPTICAL FRAMES

- EN ISO 12870 Spectacle frames

Acetate and metal frame

Chongqing Muzik Optical Co.,ltd
 1ST and 2nd floor,No.4 the capital of glasses,
 in the east of Yugong street,
 Rongchang Industrial Park, Chongqing, China

重庆睿盟进出口贸易有限公司
 Chongqing muzik optical co.,ltd

张青



Represented by Zhang Qing
 As General Director

Signed date: 10th of July 2022