


EU DECLARATION OF CONFORMITY	
REGULATION(EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on MEDICAL DEVICES	
MANUFACTURER (Name/Brand or commercial name of the manufacturer/complete legal address)	WENZHOU INTERNATIONAL ECO&TEC COOPERATION CO., LTD. 5/F FOREIGN AFFAIRS BLDG, HONGDIAN SOUTH ROAD, WENZHOU, ZHEJIANG, 325000, CHINA
MANUFACTURER)	CN-MF-000023985
AUTHORIZED EUROPEAN REPRESENTATIVE:	Humiss International B.V. Address: Joop Geesinkweg 701, 1114AB Amsterdam-Duivendrecht, the Netherlands
COMPETEN AUTHORITY	Humiss International B.V. Address: Joop Geesinkweg 701, 1114AB Amsterdam-Duivendrecht, the Netherlands ce-tech@humiss.com
AUTHORIZED EUROPEAN REPRESENTATIVE	NL-AR-000001490

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

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CORRECTIVE: SPECTACLE FRAMES FOXY

INVOICE N° :


ORDER N9:

ARTICLE CODE:

XM6001, XM6002, XM6003, XM6004, XM6005, XM6006, XM6007, X7022, X7023, X7024, X7025, X7026, X7027, X7031, X7032, X7033, X7034, X7035, X7036, GV1035, GV1037, F8780, FP1950, FP2000, FP2099, FP2102, FH2206, TA1020, T1021, X7037, X7038, X7039, X7040, X7041, X7042, X7043, X7044, X7045, X7046, X7047, X7020, X7021, X7028, FP2125, TA1021, TA1023, TA1024, TA1025, TA1028

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.

UDI-DI BASIC:	
697471200KKAQ8, 697471200KKMQY, 697471200KKQCQ, 697471200JBAP8, 697471200JBMPY, 697471200JBCPC, 697471200RSAS3, 697471200RSMST, 697471200RSCS7, 697471200WSASU, 697471200WSMTL, 697471200wSCSY, 697471200TWASR, 697471200TWMTH, 697471200TWCSV	
Classification(CLASS): class I (anexo VIII regla 1)/class I (anexo VIII regla 1)	
harmonized standards:	
generals	
-EN ISO14971:2019+A11:2021/EN ISO 10993-1:2020/ EN ISO12870:2018/ENISO 13485:2016+A11:2021	
Specifics of the product: OPTICAL	
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Signed by: Judy

Function: Manager

Date: April 10th, 2025

WENZHOU INTERNATIONAL
ECO. & TEC. CO-OPERATION CO., LTD.

