



SUPERB VISION

Superb Vision International Trading (Hangzhou) Co.,Ltd.

EU DECLARATION OF CONFORMITY		CE
<small>REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. of 5 April 2017 on MEDICAL DEVICES</small>		
MANUFACTURER (Name / Brand or commercial name of the manufacturer/complete legal address)	Superb Vision International Trading (Hangzhou) Co.,Ltd. Room 301,building 7,xixi century center,No.136 Shuanglong street,Xihu district, Hangzhou,Zhejiang,China.	
SRN (MANUFACTURER)	CN-MF-000024745	
AUTHORIZED EUROPEAN REPRESENTATIVE	SUPERBVISION OPTIK S.L.	
COMPETEN AUTHORITY	Agencia Española del Medicamento y Productos Sanitarios Campezo, 1, 28022 Madrid	
SRN(AUTHORIZED EUROPEAN REPRESENTATIVE)	CN-MF-000024745	
<p>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</p> <p>PRODUCT DESCRIPTION</p> <p>CORRECTIVE: SPECTACLE FRAMES</p> <p>BRAND NAME:   TED WALKER</p> <p>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.</p> <p>BASIC UDI-DI : 697520477KKAS7,697520477KKMSX,697520477KKCSB,697520477RSAU2,697520477RSMUS,697520477RSCU6,697520477TWAUQ,697520477TWMVG,697520477TWCUU</p> <p>Classification (CLASS): clase I (anexo VIII regla 1)</p> <p>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.</p> <p>Specifics of the product: OPTICAL</p> <p>The products:</p> <ul style="list-style-type: none"> -Comply with European standards EN ISO 12870: 2016 / EN 16128 (if applicable) -Are in conformity with the EU REGULATION 2017-745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices; -Are marked "CE"; -Are in conformity with the general obligation of security requested by 2001/95/CEE Directive and all its updates. 		
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Signed by: Chengyi Dai

Function: Vice president

超视国际贸易(杭州)有限公司
SUPERB VISION INTERNATIONAL TRADING (HANGZHOU) CO., LTD.

Date and place: 21/11/2022 Hangzhou China