

EU DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745 ACCORDING TO ANNEX IV OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.
of 5 April 2017 on MEDICAL DEVICES,



MANUFACTURER	MONDOTTICA MICHAEL HOUSE, RIVERSIDE BUSINESS PARK, RENNIE HOGG ROAD NOTTINGHAM , UK NG2 1RX Tel: +44 (0) 115 9677 912	
SRN		GB-MF-000018978
AUTHORIZED EUROPEAN REPRESENTATIVE	MYM SOPORTE TÉCNICO Y DE CALIDAD, S.L. (MYM STC, S.L.) Avenida de los Rosales, 32. 28935. Móstoles (Madrid) Spain. direccion@mym-stc.com / www.mym-stc.com.es	
SRN		ES-AR-000017300
<p>THE MANUFACTURER DECLARES UNDER THEIR RESPONSIBILITY THAT THE PRODUCTS DESCRIBED 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 FRAMES FOR OPHTHALMIC GLASSES</p> <p>INTENDED USE:</p> <p><i>The frame is an essential accessory so that the ophthalmic lenses can be carried and compensate for a visual defect.</i></p>		
Classification	CLASS I, Rule 1, Annex VIII, Chapter III, Regulation (EU) 2017/745	
PRODUCT FAMILY	BASIC UDI-DI	
PLASTIC FULL RIM	4894327FFPJ4	
METAL FULL RIM	4894327FFMHW	
MIXED FULL RIM	4894327FFXJL	
PLASTIC HALF RIM	4894327FHPJA	
METAL HALF RIM	4894327FHMJ4	
MIXED HALF RIM	4894327FHXJS	
DENOMINATION AND COMMERCIAL NAME: see annex 1 ARTICLE CODE: available on request		
<ul style="list-style-type: none">Conformity assessment procedureName and ID of the notified bodyCertificate CE number		N.A N.A N.A
The manufacturing quality Management System follows the standards		EN ISO 9001:2015
Applied standard & common Specification: EN ISO 14971 / EN ISO 15223-1/ EN 1041 / EN ISO 10993-1 +AC:2010 / EN 62366 / EN ISO 12870:2016		
Signed by: Mark Gilbert Function: Director Date: 02/09/2024 Place of Issue and SRN: Mondottica Nottingham, GB-MF-000018978' Signature:		

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ANNEX 1

A. PRODUCT LIST OF BRANDS (PRODUCT FAMILY AND BRANDS)

1	Taylor Morris London PLASTIC & METAL
2	Sunday Somewhere PLASTIC & METAL

Signed:

Mark Gilbert

DATE: 02/09/2024