

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
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SRN	GB-MF-000018978
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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
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SRN	ES-AR-000017300
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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,

**PRODUCT DESCRIPTION
FRAMES FOR OPHTHALMIC GLASSES**

INTENDED USE:

The frame is an essential accessory so that the ophthalmic lenses can be carried and compensate for a visual defect.

Classification	CLASS I, Rule 1, Annex VIII, Chapter III, Regulation (EU) 2017/745
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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	4894327FHXS

DENOMINATION AND COMMERCIAL NAME: see annex 1
ARTICLE CODE: available on request

<ul style="list-style-type: none"> • Conformity assessment procedure • Name and ID of the notified body • Certificate CE number 	N.A N.A N.A
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The manufacturing quality Management System follows the standards	EN ISO 9001:2015
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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: 11/12/2023
Signature:

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

1	Ted Baker Optical Frames PLASTIC & METAL
2	Hackett Optical Frames PLASTIC & METAL
3	United Colors of Benetton Optical Frames PLASTIC & METAL
4	Christian Lacroix Optical Frames PLASTIC & METAL
5	Pepe Jeans Optical Frames PLASTIC & METAL
6	Maje Optical Frames PLASTIC & METAL
7	Sandro Optical Frames PLASTIC & METAL
8	Joules Optical Frames PLASTIC & METAL
9	Scotch and Soda Optical Frames PLASTIC & METAL
10	Ducati Optical Frames PLASTIC & METAL
11	Sergio Tacchini Optical Frames PLASTIC & METAL
12	Karen Millen Optical Frames PLASTIC & METAL
13	Le Coq Sportif Optical Frames PLASTIC & METAL
14	Cath Kidston Optical Frames PLASTIC & METAL
15	Vivienne Westwood Optical Frames PLASTIC & METAL
16	All Saints Optical Frames PLASTIC & METAL
17	Reebok Optical Frames PLASTIC & METAL
18	Florence by Mills Optical Frames PLASTIC & METAL

Signed

Mark Gilbert

DATE: 11/12/2023