

Mondottica Ophthalmic Instructions for Use

Frame Purpose

Mondottica ophthalmic frames are class I medical devices (Rule 1 Chapter III of Annex VIII of EU 2017/745). For intended use of ophthalmic frames, a prescribed ophthalmic lens is required to be mounted into the frame's aperture, enabling correction or improvement of a person's visual acuity.

Mondottica ophthalmic frames are intended to be dispensed to the user by a qualified or experienced practitioner, ensuring the users' facial measurements and prescribed ophthalmic lenses have been considered, resulting in a suitable ophthalmic frame and lens combination for the user.

Mondottica ophthalmic frames are designed to be capable of minor adjustments to the frames temples and nose pads to ensure a secure and comfortable fit for the user. Any adjustments to the frame should be done so by a qualified or experienced practitioner.

Mondottica ophthalmic frames are manufactured in compliance with the requirements set out in (EU) Regulation 2017/745 and the harmonized standard EN ISO 12870.

Mondottica Sunglasses are manufactured in compliance with the requirements set out in PPE Regulation 2016/425

Frame Storage & Cleaning

Mondottica ophthalmic and Sunglass frames should ideally be stored in their protective case at a temperature between -10°C and +35°C.

Mondottica recommends cleaning its ophthalmic and sunglass frames with mild soap and a micro fibre cloth. Frames should then be dried using a micro fibre cloth.

Do not use solvents or household cleaning products as these may affect the frames colouring and/or tone, design, or characteristics.

Frame Markings

Mondottica ophthalmic and sunglass frames are manufactured in compliance with EN ISO 12870, each frame is imprinted with model codes and sizing information on the inside of the left-hand temple. A three-digit alphanumeric production code can be found on the inside right hand temple tip.

Frame Risks

Whilst every effort is taken to prevent adverse contact reactions, these cannot be entirely ruled out in highly sensitive or allergic individuals.

Mondottica ophthalmic frames are produced with clear demo lenses for the purpose of frame stability in storage, transit and frame display purposes.

Frames exposed to high temperatures, for example the sun, are at risk of deformation (frames with acetate structure).

In the case Mondottica ophthalmic and sunglass frames come into contact with contaminants such as chemical products, make up or sun lotion, frames should be immediately cleaned using the above cleaning instructions.

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Instructions For Use	Aimie Murfin	Ryan Rontree	Compliance
Version	Last Issue Date	Next Review Date	Regulation
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Frame Queries

In the first instance, any questions relating to Mondottica frames should be directed to the store where the frame was purchased. In the event the store cannot be contacted, or you are unhappy with the response forward the query to Frame Manufacturer (details below)

Serious Incidents involving Frames

In the unlikely event of a serious incident involving a Mondottica ophthalmic or sunglass frame, details should be reported to the Frame Manufacturer (below) and a competent authority in the member state the user/patient is established.

Disposal and Recycling of Frames

When disposing of a Mondottica frame, there are multiple ways in doing this safely and sustainably, whilst glasses/spectacle frames are unable to be recycled in the general household recycling systems, there are many glasses/Spectacle Frame recycling schemes established internationally such as Lions Club and Retrospecced that help reduce the amount of waste going to landfill.

Frame Manufacturer

Mondottica, Michael House, Riverside Business Park, Nottingham, England. NG2 1RX

www.mondottica.com / E: sales@mondottica.com / T: +44 (0) 1159 677 912

Mondottica EU Representative

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Sunglass Declaration of Conformity

For Declaration of Conformities for sunglasses please see doc.mondottica.com

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