



EU Declaration of Conformity

M040399 - OPHTHALMIC DRESSINGS - OTHER

Eye Shields

Intended purpose of the device(s):

Eye shields are used after surgery to protect the eye and hold dressings in place. They are made of transparent Polycarbonate shatterproof plastic in a universal shape for use over either eye. Holes in the eye shield provide ventilation. Adult and children's sizes are available.

Basic UDI-DI: ++B091EyeShieldsZA

Product Name	Part #	Quantity	UDI
Eye Shield, Adult (Bulk)	14100	600	+B091141001Q
Eye Shield, Child (Bulk)	14101	600	+B091141011R
Eye Shield, Adult (dz)	14203	12	+B091142031U
Eye Shield, Child (dz)	14204	12	+B091142041V
Orange Eye Shield	14205	1	+B091142050V
Orange Eye Shield	14205	10	+B091142051W
Orange Eye Shield	14205	100	+B091142052X
Orange Eye Shield	14205	200	+B091142053Y
Orange Eye Shield	14205	1000	+B091142054Z

Class I in accordance with EU 2017/745 Annex VIII Chapter 3 (4.1) Rule 1**Manufacturer:**

Gulden Ophthalmics
225 Cadwalader Avenue
Elkins Park, PA 19027
SRN: US-MF-000008608

European Authorized Representative:

Qarad EC-REP BV
Pas 257
2440 Geel
Belgium
SRN: BE-AR-000000040

This declaration of conformity is issued under the sole responsibility of Gulden Ophthalmics in accordance with Article 19, after drawing up the technical documentation in Annexes II and III. We hereby declare that the medical device(s) specified meet the provisions of EU Regulation 2017/745 for medical devices.

Technical documentation is retained at the premises of the manufacturer and available to the authorized representative and/or competent authorities as required.

Toni Fisher

Quality Manager

On behalf of Gulden Ophthalmics·225 Cadwalader Avenue·Elkins Park, PA 19027

13 September 2021