

## DECLARATION OF CONFORMITY

### PRODUCT IDENTIFICATION

**Product Name:** Plastic Ocular Shield  
**Basic UDI-DI** 697660100US  
**GMDN** 64271 – Radiation/mechanical corneal shield, reusable  
**Intended Purpose** The plastic ocular shields are used to protect the patient during medical treatment which involves scalpels, electro-cutters or other energy sources (ex: RF systems) requiring protective plastic ocular shields as the metal ocular shields would be conductive.

### Photo



Plastic Ocular Shield, black



Plastic Ocular Shield, black, with handle



Plastic Ocular Shield, yellow



Plastic Ocular Shield, yellow, with handle

Product Code	Description	UDI-DI	Product Code	Description	UDI-DI
23-201B	Plastic Ocular Shield (extra small), black	10697660002627	23-201Y	Plastic Ocular Shield (extra small), yellow	10697660002702
23-201BH	Plastic Ocular Shield (extra small), black with handle	10697660002641	23-201YH	Plastic Ocular Shield (extra small), yellow with handle	10697660002726
23-202B	Plastic Ocular Shield (small), black	10697660002788	23-202Y	Plastic Ocular Shield (small), yellow	10697660002863
23-202BH	Plastic Ocular Shield (small), black with handle	10697660002801	23-202YH	Plastic Ocular Shield (small), yellow with handle	10697660002887
23-204B	Plastic Ocular Shield (medium), black	10697660002948	23-204Y	Plastic Ocular Shield (medium), yellow	10697660003020
23-204BH	Plastic Ocular Shield (medium), black with handle	10697660002962	23-204YH	Plastic Ocular Shield (medium), yellow with handle	10697660003044
23-206B	Plastic Ocular Shield (large), black	10697660003105	23-206Y	Plastic Ocular Shield (large), yellow	10697660003181
23-206BH	Plastic Ocular Shield (large), black with handle	10697660003129	23-206YH	Plastic Ocular Shield (large), yellow with handle	10697660003204

### MANUFACTURER

**Name:** Oculo-Plastik, Inc.  
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**Representative:** Derek Fletcher, Regulatory Affairs Coordinator

### AUTHORIZED REPRESENTATIVE IN EUROPE

**Name:** MedEnvoy Global BV  
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 2595 AM The Hague  
**Country:** The Netherlands  
**SRN:** NL-AR-000024028

## MEANS OF CONFORMITY

Oculo-Plastik, Inc. declares that the products listed have been classified as Class I under Annex VIII, Rule 5 and they are in conformity with Regulation (EU) 2017/745 of the European Parliament. Conformity is declared with reference to the following common specifications and standards: ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-7:2008; ISO 10993-10:2010; ISO 13485:2016; EN ISO 14971:2012; EN ISO 15223-1:2021; ISO 17665-1:2006, AAMI TIR No.12-2004; EN 556-2:2003; ASTM D648, ASTM D1525; ASTM D638; ASTM D570; ASTM C177; ISO 11737-1:2018; (EC) No 1272/2008; (EC) No 1907/2006; . This declaration is issued under the sole responsibility of Oculo-Plastik, Inc.



## SIGNATURE

Representative : Derek Fletcher, Regulatory Affairs Coordinator  
Date: 19/07/2022  
Location: Montréal, Québec, Canada

