

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product Name: Cox® Stainless Steel Ocular Laser Shield
Basic UDI-DI 697660101UU
GMDN 64271 – Radiation/mechanical corneal shield, reusable
Intended Purpose The Cox Stainless Steel Ocular Laser Shields are used to protect the patient’s eyes during IPL and laser medical treatments close to the patient’s eyes and on the face.

Photo



COX II



COX II with Handle

Product Code	Description	UDI-DI	Product Code	Description	UDI-DI
21-261	Stainless Steel Ocular Laser Shield, extra-small (non glare) with a suction cup	10697660001415	21-264	Stainless Steel Ocular Laser Shield, medium (non glare) with a suction cup	10697660001651
21-261HL	Stainless Steel Ocular Laser Shield, Left, extra-small (non glare) with handle	10697660001439	21-264HL	Stainless Steel Ocular Laser Shield, Left, medium (non glare) with handle	10697660001675
21-261HR	Stainless Steel Ocular Laser Shield, Right, extra-small (non glare) with handle	10697660001477	21-264HR	Stainless Steel Ocular Laser Shield, Right, medium (non glare) with handle	10697660001712
21-262	Stainless Steel Ocular Laser Shield, small (non glare) with a suction cup	10697660001538	21-266	Stainless Steel Ocular Laser Shield, large (non glare) with a suction cup	10697660001774
21-262HL	Stainless Steel Ocular Laser Shield, Left, small (non glare) with handle	10697660001552	21-266HL	Stainless Steel Ocular Laser Shield, Left, large (non glare) with handle	10697660001798
21-262HR	Stainless Steel Ocular Laser Shield, Right, small (non glare) with handle	10697660001590	21-266HR	Stainless Steel Ocular Laser Shield, Right, large (non glare) with handle	10697660001835

MANUFACTURER

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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; EN ISO 10993-5:2009; ISO 10993-7:2008; ISO 10993-10:2010; ISO 17665-1:2006; ISO 11737-1:2018; ISO 13485:2016; EN ISO 14971:2012; EN ISO 15223-1:2016; ASTM F899-20. 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

