

## DECLARATION OF CONFORMITY

### PRODUCT IDENTIFICATION

Product Name: External Laser Shields Durette® III and IV  
Cat. Numbers: 21-440; 21-440N; 21-440T; 21-442; 21-442R; 21-445; 21-445R; 21-536; 21-537;  
21-550; 21-550N; 21-550T; 21-552; 21-552R; 21-555; 21-555R; 21-660S; 27-6545.

### MANUFACTURER

Name: Oculo-Plastik, Inc.  
Address: 200 rue Sauvé ouest,  
Montréal, Québec H3L 1Y9  
Country: Canada  
Representative: Derek Fletcher, QA/RA

### NOTIFIED BODY


Name: SGS United Kingdom Limited  
ID: 0120  
EN ISO 13485:2012 Certificate No.: US04/61030  
Directive 93/42/EEC Certificate No.: US05/66076

### AUTHORIZED REPRESENTATIVE IN EUROPE

Name: EMERGO EUROPE  
Address: Prinsessegracht 20  
2514 AP The Hague  
Country: The Netherlands

### MEANS OF CONFORMITY

Oculo-Plastik, Inc. declares that the products listed have been classified as Class I Annex IX, Rule 1 and are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC per annex VII, as transposed in the national laws of the Member States, and conforms to standards ASTM F899 (2007); EN 1041 (2008); ISO 10993-5 (2009); EN ISO 13485 (2012); EN ISO 14971 (2012); ISO 15223-1 (2016); and MPIF 35 (2016).



### SIGNATURE

Representative : Derek Fletcher, QA/RA  
Date: 2018-05-31  
Location: Montréal, Québec, Canada

