

## DECLARATION OF CONFORMITY

### PRODUCT IDENTIFICATION

Product Name: Durette® Plastic External Shields  
Cat. Numbers: 23-442B; 23-442W; 23-445B.

### 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 EN 1041 (2008); EN ISO 13485 (2012); EN ISO 14971 (2012); and ISO 15223-1 (2016).



### SIGNATURE

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