

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product Name: Durette® II External Ocular Shields
Cat. Numbers: 21-330; 21-334; 21-334R; 21-335; 21-335R; 27-6530.

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 (12b); EN 1041 (2008); ISO 10993-5 (2009); EN ISO 13485 (2012); EN ISO 14971 (2012); ISO 15223-1 (2016).



SIGNATURE

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