

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product Name: Plastic Ocular Shield
Cat. Numbers: 21-204BV; 23-201B; 23-201BE; 23-201BH; 23-201BHE; 23-201Y;
23-201YE; 23-201YH; 23-201YHE; 23-202B; 23-202BE; 23-202BH;
23-202BHE; 23-202Y; 23-202YE; 23-202YH; 23-202YHE; 23-204B;
23-204BE; 23-204BH; 23-204BHE; 23-204Y; 23-204YE; 23-204YH;
23-204YHE; 23-206B; 23-206BE; 23-206BH; 23-206BHE; 23-206Y;
23-206YE; 23-206YH; 23-206YHE.

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

SIGNATURE

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