

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product Name: Cox® Ocular Laser Shield
Cat. Numbers: 21-261; 21-261E; 21-261HL; 21-261HLE; 21-261HLR; 21-261HLRE; 21-261HR; 21-261HRE; 21-261HRR; 21-261HRRE; 21-261R; 21-261RE; 21-262; 21-262E; 21-262HL; 21-262HLE; 21-262HLR; 21-262HLRE; 21-262HR; 21-262HRE; 21-262HRR; 21-262HRRE; 21-262R; 21-262RE; 21-264; 21-264E; 21-264HL; 21-264HLE; 21-264HLR; 21-264HLRE; 21-264HR; 21-264HRE; 21-264HRR; 21-264HRRE; 21-264R; 21-264RE; 21-266; 21-266E; 21-266HL; 21-266HLE; 21-266HLR; 21-266HLRE; 21-266HR; 21-266HRE; 21-266HRR; 21-266HRRE; 21-266R; 21-266RE.

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 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

