

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product Name: LaserSecure® Instrumentation
(Forceps, Retractors, Lid Clamps, Lid Plates, Swab, Trelles, Sutcliffe, Jaeger)
Cat. Numbers: 21-212R; 21-275; 21-275R; 21-276; 21-276R; 21-278R; 21-279R; 21-287; 21-287R;
21-288R; 21-289; 21-289R; 21-290R; 21-292; 21-292R; 21-295; 21-295R; 21-296;
21-296R; 21-310; 21-310R; 21-312; 21-312R; 21-314; 21-314R; 21-316; 21-316R;
21-318; 21-318R; 21-319; 21-319R; 21-322; 21-322R; 21-322S; 21-323; 21-323L;
21-323R; 25-103; 25-103R; 25-105; 25-105R; 25-109; 25-109R; 25-112; 25-112R;
25-211; 25-211R; 25-222; 25-222R; 25-224; 25-224R; 25-226; 25-226R; 28-010;
28-010R; 28-012; 28-012R.

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 6 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