TOPCON

DECLARATION OF CONFORMITY

Manufacturer	Name: TOPCON CORPORATION Address: 75-1, Hasunuma-cho, Itabashi-ku, Tokyo, 174-8580, JAPAN
Manufacturing facility	Name: TOPCON YAMAGATA Co., Ltd. Address: 547 Aza Ishida Oaza Urushiyama, Yamagata-shi, Yamagata-ken, 990-2196, JAPAN
EU Representative	Name: TOPCON EUROPE MEDICAL B.V. Address: Essebaan 11, 2908 LJ, Capelle a/d Ijssel, THE NETHERLANDS
Name of device	SLIT LAMP
Model No.	SL-2G
Product covered	S/N:2860875,2863485,2863488,2863771,2863787,2863955,2863957, 2863958, 2863965~2863992, 2864400～,2865160
Classification	CLASS I (according to MDD ANNEX IX rule12)
Conformity Assessment Route	ANNEX VII of MDD

We herewith declare that the above mentioned product meets the provisions of the Council Directive 93/42/EEC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.
The manufacturer is exclusively responsible for the declaration of conformity.

Standards Applied

EN ISO13485: 2016
EN 60601-1:2006/A1:2013
EN 60601-1-2: 2015
EN 62366: 2008
For other applied standards, see the applied standard list in "B-06 Standards applied" of the Technical Document File.
Refer to the "IEC60601-1-2:2014 Conformity check report (TDF B-02-4)" for conformity with requirements other than certain items described in the above report.

CE

Place Tokyo, Japan
Date of issue 15 Jan., 2020

T. Horiuchi

Tadahiko Horiuchi
Senior Manager
Quality Assurance Dept.
Quality Assurance Div.
TOPCON CORPORATION

4462897991

Vertimas iš anglų kalbos į lietuvių

ATITIKTIES DEKLARACIJA

Gamintojas
Pavadinimas: TOPCON Korporacija
Adresas: 75-1, Hasunuma- cho, Itabashi- ku, Tokyo, 174- 8580, Japonija

Gamintojo padalinys
Pavadinimas: TOPCON YAMAGATA., LTD
Adresas: 547 Aza Ishida Oaza Urushiyama, Yamagata- shi
Yamagata-ken, 990-2196 Japonija

Atstovas Europoje
Pavadinimas: TOPCON EUROPE B.V
Adresas: Essebaan 11, 2908 LJ, Capelle a/d Ijssel, Nyderlandai

Prietaisas: PLYŠINĖ LEMPA

Modelio Nr. SL-2G

Klasifikacija: Klasė I (pagal MDD PRIEDAS IX taisyklė 1)

Atitikimas MDD PRIEDAS VII

Tvirtiname, kad medicinos prietaisas atitinka pagrindinius EC Direktyvos 93/42/EEC reikalavimus.

Standartų atitikimas EN ISO13485:2016
EN 60601- 1: 2006/ A1: 2013
EN 60601-1-2: 2015
EN 62366: 2008

Vieta: Tokijas, Japonija

/PARAŠAS/

Data: 2020 sausio 15 d.

Tadahiko Horiuchi
Vyresnysis direktorius
Oftalmologiniai & Medicinos Instrumentai
Kokybės kontrolės departamentas
TOPCON KORPORACIJA