

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	COMPUTERIZED TONOMETER
Model No.	CT-1P
Product covered	S/N: 2631900,2631901,2631993,2632032,2632033,2632100 ~
Classification	CLASS IIa (according to MDD ANNEX IX rule 10)
Conformity Assessment Route	ANNEX V + VII of MDD

We herewith declare that the above mentioned products meet 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 ISO 13485:2016 EN 60601-1:2006+A12:2014 EN 60601-1-6:2010+A1:2015 EN 60601-1-2:2015 EN 62304: 2006+A1: 2015 EN 62366-1: 2015 EN ISO15004-1:2009 ISO15004-2:2007 EN ISO14971:2019 ISO 10993-1:2018 EN ISO 15223-1:2016 EN 1041:2008+A1:2013 ISO 8612:2009
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Notified Body	Name: TÜV SÜD Product Service GmbH Address: Ridlerstrasse 65 80339 Munchen Germany Identification No.: 0123
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EC Certificate

No.: G2 021020 0108 Rev.00
Date of issue: 08 .Nov 2019



Place Tokyo, Japan
Date of issue 1 Feb., 2021

A handwritten signature in black ink, appearing to read 'K. Nojima', is written over a horizontal line.

Kazuyuki Nojima
Senior Manager
Quality Assurance Dept.
Quality Assurance Div.
TOPCON CORPORATION

Vertimas iš anglų kalbos į lietuvių kalbą

ATITIKTIES DEKLARACIJA



Gamintojas

Pavadinimas: TOPCON Korporacija

Adresas: 75-1, Hasunuma-cho, Itabashi-ku, Tokyo, 174-8580, Japonija

Atstovas Europoje

Pavadinimas: TOPCON EUROPE MEDICAL B.V

Adresas: Esse Baan 11, 2908 LJ, Capelle a/d IJssel, Nyderlandai

Prietaisas: Kompiuterinis tonometras

Modelio Nr. CT-1P

Serijos Nr. S/N: 2631900,2631901,2631993,2632032,2632033,2632100 ~

Klasė Ila (pagal MDD IX priedo 10 taisyklę)

Atitikties įvertinimas MDD V + VII priedai

Aš, žemiau pasirašęs, tvirtinu, kad medicinos prietaisas atitinka pagrindinius EC Direktyvos 93/42/EEC reikalavimus, perkeltus į nacionalinę teisę. Visi dokumentai saugomi pas gamintoją.

Standartai EN 60601-1:2006+A12:2014
EN 60601-1-6:2010+A1:2015
EN 60601-1-2:2015
EN 62304: 2006+A1: 2015
EN 62366-1: 2015
EN ISO15004-1:2009
ISO15004-2:2007
EN ISO14971:2019
ISO 10993-1:2018
EN ISO 15223-1:2016
EN 1041:2008+A1:2013
ISO 8612:2009

Notifikavimo atstovas TUV SUD Produktų servizas GmbH
Adresas: Zertifizierstelle Ridlerstrasse 65 80339 Miunchenas
Vokietija
Identifikavimo Nr. 0123

CE sertifikatas NR.: G2 021020 0108 Rev.00
Išleista: 2019 m. Balandžio 8 d.

Vieta: Tokyo, Japonija
Išdavimo data: 2021-02-01
/PARAŠAS/

Takashi Horiuchi
Vyresnysis direktorius
Kokybės kontrolės departamentas
TOPCON KORPORACIJA