



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	AUTO KERATO-REFRACTOMETER
Model No.	KR-800
Product covered	418479900 (SN: 4763883, 4767632, 4768956, 4769600~, 4769800, 4770144, 4770298, 4770850, 4771805) 418479950 (SN: 4773617, 4773618, 4773659, 4773663~)
Classification	CLASS I with measuring function (according to MDD ANNEX IX rule 12)
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 60601-1-2: 2015 EN 60601-1-6:2010+A1:2015 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 10342:2010 ISO 10343:2014
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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.: G2M 021020 0109 Rev.00
Date of issue: 8 Nov. 2019



Place Tokyo, Japan
Date of issue 9 Jun., 2023

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

Isao Hiyoshi
Senior Manager
Eye Care Quality Assurance Dept.
Quality Assurance Div.
TOPCON CORPORATION