



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 S/N: 4769600~

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.

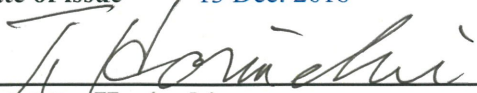
Standards Applied EN ISO 13485:2016
EN60601-1:2006/A1:2013
EN 60601-1-2: 2015
EN 62304: 2006/AC: 2008
EN 62366: 2008
For other applied standards, see the applied standard list in "B-06 Standards applied" of the Technical Document File.

Notified Body Name: TÜV SÜD Product Service GmbH
Address: Ridlerstrasse 65 80339 Munchen Germany
Identification No.: 0123

EC Certificate No.: G2M 18 01 21020 102
Date of issue: 5 Apr. 2018



Place Tokyo, Japan
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