



## 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.

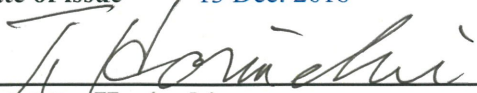
**Standards Applied** EN ISO 13485:2016  
EN60601-1:2006/A1:2013  
EN 60601-1-2: 2015  
EN 62304: 2006/AC: 2008  
EN 62366: 2008  
For other applied standards, see the applied standard list in "B-06 Standards applied" of the Technical Document File.

**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  
Date of issue 13 Dec. 2018

  
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Quality Assurance Div.  
TOPCON CORPORATION