

## DECLARATION OF CONFORMITY

<b>Manufacturer</b>	Name: TOPCON CORPORATION Address: 75-1, Hasunuma-cho, Itabashi-ku, Tokyo, 174-8580, JAPAN
<b>Manufacturing facility</b>	Name: TOPCON YAMAGATA Co., Ltd. Address: 547 Aza Ishida Oaza Urushiyama, Yamagata-shi, Yamagata-ken, 990-2196, JAPAN
<b>EU Representative</b>	Name: TOPCON EUROPE MEDICAL B.V. Address: Essebaan 11, 2908 LJ, Capelle a/d IJssel, THE NETHERLANDS
<b>Name of device</b>	3D Optical Coherence Tomography
<b>Model No.</b>	3D OCT-1
<b>Identifier</b>	(Type: Maestro2)
<b>Product covered</b>	S/N: AB9000311, AB9000328, AB9000406, AB9000420, AB900577, AB9000732, AB9001637, AB9001644, AB9001652, AB9001655, AB9001658, AB9001660, AB9001663, AB9001693, AB9001700, AB9001705, AB9001707, AB9001716~AB9001718, AB9001720, AB9001721, AB9001730, AB9001733, AB9001734, AB9001736, AB9001738, AB9001742, AB9001743, AB9001745~AB9001747, AB9001816~AB9001820, AB9001822, AB9001825~AB9001829, AB9001831, AB9001835, AB9001836, AB9001843, AB9001844, AB9001846, AB9001847, AB9001849~AB9001858, AB9001867, AB9001868, AB9001870, AB9001871, AB9001873, AB9001878~AB9001880, AB9001882, AB9001885, AB9001886, AB9001888~AB9001901, AB9001903, AB9001904, AB9001906, AB9001912~AB9001922, AB9001924~AB9001947, AB9001949, AB9001951~AB9001973, AB9001975~AB9001977, AB9001981~, AB9070166, AB9070237, AB9070252, AB9070256, AB9070285, AB9070318
<b>Classification</b>	CLASS IIa (according to MDD ANNEX IX rule 10)
<b>Conformity Assessment Route</b>	ANNEX V + 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 ISO 13485:2016  
EN 60601-1:2006+A12:2014  
EN 60601-1-6:2010+A1:2015  
IEC 60825-1:2007  
EN 60601-1-2:2015  
EN 62304: 2006+A1: 2015  
EN 62366-1: 2015  
ISO15004-1:2006  
ISO15004-2:2007  
ISO 14971:2019  
ISO 10993-1:2018  
IEC 82304-1:2016  
EN ISO 15223-1:2016  
EN 1041:2008+A1:2013  
ISO 16971:2015  
ISO 10940:2009

**Notified Body**

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

**EC Certificate**

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



Place Tokyo, Japan  
Date of issue 10 Sep., 2021

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TOPCON CORPORATION