

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 COMPU VISION

Model No. CV-5000
CV-5000Lite*
CV-5000 PRO*

Product covered (CV-5000) S/N: 2115101 ~
(CV-5000Lite*) S/N: 2215101 ~
(CV-5000 PRO*) S/N: 2630101 ~

Classification CLASS I (according to MDD ANNEX IX rule 12)

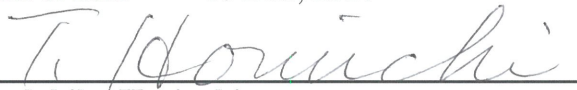
Conformity Assessment Route ANNEX VII of MDD

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 ISO13485: 2012/AC: 2012
EN 60601-1:2006/A1:2013
EN 60601-1-2: 2007/AC: 2010
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.



Place Tokyo, Japan
Date of issue 18 Dec., 2017


Tadahiko Horiuchi
Senior Manager
Quality Assurance Dept.
Quality Assurance Div.
TOPCON CORPORATION

*Lite and PRO is a catalogue number