



EC DECLARATION OF CONFORMITY (No.DC-S07-F)

Manufacturer: Ohira Co., Ltd.

European Representative: Fausto Guzzetti
(Shin-Nippon Technical Center)
Via Solferino, 5 21057 Olgiate Olona(VA), Italy

Product: Trade Name: Applanation Tonometer SL-TM
Description: Tonometer, ophthalmic

Classification: Class I with measuring function
Rule 5 according to Annex IX of the MDD

Conformity Assessment Route: Annex V applied

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

General applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC
(MDD 93/42/EEC)

Standards: Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are:

EN ISO 15004-1:2009	Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2006)
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003)

Notified Body: SGS UNITED KINGDOM LIMITED
202B Worle Parkway, Weston-Super-Mare, BS22 6WA,
United Kingdom
ID #: 0120

EC Certificate: Standard: EN ISO13485:2003
EC Certificate #: JP08/040116

Signature: *Hiroji Ohira* Date: 2010.03.21
Name Hiroji Ohira
Position President