



NIDEK CO., LTD.

34-14, Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
Manufacturers, Exporters & Importers of Ophthalmic Instruments, and Opto-Electronics Instruments

TEL +81-533-67-6611
FAX +81-533-67-6610
URL <http://www.nidek.co.jp>
<http://www.nidek.com>

Document No.: BRQF016NT-530EU01

DECLARATION OF CONFORMITY

Manufacturer's name NIDEK Co. Ltd.
Manufacturer's address 34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
NIDEK s.a.
European Representative Europarc, 13 rue Auguste Perret, 94042 Creteil, France
Identification of device Noncontact Tonometer
Model No. NT-530
Classification(Annex IX, MDD) II a
Starting from this serial number 230013

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.

DIRECTIVES

General applicable directives:

Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.

Standards :

Applicable Standards to this product are :

ISO13485, ISO14971, IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, ISO8612, ISO15004-1, ISO15004-2, EN980, IEC/TR60878

Notified Body : TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

Certificate : G1 08 07 23653 046 (Annex II , Section 3 of MDD)

Date CE Mark was affixed : September 10, 2008

Place: Aichi, Japan

Date: September 10, 2008

Signed by

Kan Ohtsuki
General Marketing Manager,
NIDEK Co., Ltd.