



**NIDEK CO., LTD.**

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

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## 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 Refractor  
Model No. RT-5100  
Classification(Annex IX, MDD) I  
Starting from this serial number 730001

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 :

Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are :  
ISO13485, ISO14971, ISO13666, ISO15004, EN980, IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, IEC/TR60878

Date CE Mark was affixed : December 9, 2005

Place: Aichi, Japan

Signed by

Date: December 9, 2005

Kan Ohtsuki  
Quality Executive Representative,  
NIDEK Co., Ltd.