



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 product Refractor

Model No. RT-3100

Classification(Annex IX, MDD) I

Starting from this serial number Unit type : 820225
Stand type : 720161

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

DIRECTIVES

General applicable directives:

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

Standards :

Applicable Standards to this product are :

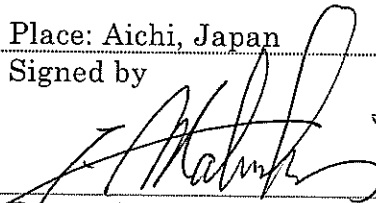
ISO13485, ISO14971, IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, IEC60601-1-6, IEC62304, ISO13666, ISO15004-1, EN980, IEC/TR60878

Date CE Mark was affixed : December 25, 2008

Place: Aichi, Japan

Date: February 19, 2010

Signed by



Tsuneo Matsuhisa
Senior Managing Director
NIDEK Co., Ltd.