





DECLARATION OF CONFORMITY

Manufacturer's name NIDEK Co. Ltd.
 Manufacturer's address 34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
 European Representative NIDEK s.a.
Europarc, 13 rue Auguste Perret, 94042 Créteil, France
 Identification of device Microperimeter
 Model No. MP-3
 Classification(Annex IX, MDD) II a
 Category (for RoHS) 8

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer. The supporting technical documentation is also retained at NIDEK s.a., Europarc, 13 rue Auguste Perret, 94042 Créteil, France.

DIRECTIVES, STANDARDS and NOTIFIED BODY

General applicable directives	Standards	Notified Body	Date CE Mark was affixed
COUNCIL DIRECTIVE 93/42/EEC concerning medical devices.	EN ISO13485, EN ISO14971, IEC60825-1, ISO10940, EN ISO 15004-1, ISO 15004-2, IEC60601-1, IEC60601-1-2, IEC60601-1-6, IEC62304, IEC62366, ISO15223-1, JIS Z 0150, EN980	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany Certificate : G1 13 07 23653 126 (Annex II , Section 3 of MDD)	March 26, 2015 
COUNCIL DIRECTIVE 2011/65/EU concerning restriction of the use of certain hazardous substances.	EN50581		March 26, 2015 

Place: Aichi, Japan
Signed by

Effective date : March 26, 2015


Kan Ohtsuki
Corporate Advisor,
NIDEK Co., Ltd.

Date of signature : Mar 26, 2015