

# EC Declaration of Conformity

# POTEC

## The EC Directives covered by this Declaration

**93/42/EEC (MDD)** COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, amended by 2007/47/EC

**Manufacturer:** **POTEC Co., Ltd.**  
40-4, Techno 2-ro, Yuseong-gu, Daejeon, 34015, Korea  
( TEL: +82-42-632-3536 / FAX: +82-42-632-3537 / e-mail:webmaster@potec.biz )

**EC Authorized Representative:** **Medical Device Safety Service GmbH**  
Schiffgraben 41, 30175 Hannover, Germany

## The Product(s) Covered by this Declaration

Product description: Auto Ref-Keratometers  
Type designation(s): PRK-5000, PRK-6000, PRK-7000, PRK-8000  
MDD (93/42/EEC) Classification: Class I with measuring function (Rule 12 of Annex IX)  
Conformity Assessment Route: Annex II w/o.4, 93/42/EEC  
Start of CE Marking: 21.09.2005 (PRK-5000); 19.09.2008 (PRK-6000);  
17.10.2013 (PRK-7000); 29.12.2016 (PRK-8000)

## The Basis on which Conformity is being declared

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:

- All applied harmonized standards were adopted under the EC Directive 93/42/EEC and published in the Official Journal of the European Communities

This Declaration of Conformity is based on the EC Directive 93/42/EEC, Annex II w/o.4 and supported by the TÜV NORD CERT GmbH (0044) certificate, with reference to articles 1 and 3 of the directive 93/42/EEC.

**Notified Body:** TÜV NORD CERT GmbH  
Langemarckstraße 20, 45141 Essen, Germany

**Identification No.:** 0044

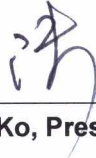
**EC Certificate No.:** 44 232 117847

We, Potec Co., Ltd., hereby declare under our sole responsibility that the above-mentioned products comply with the essential requirements and provisions of Council Directive 93/42/EEC.

**Valid of this Declaration:** 13.12.2019 - 26.05.2024

Daejeon, 31.08.2020

**Place, Date of Issue:**

  
**An-Soo Ko, President**