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.**
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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-8000 (RC-900, CX 1000)
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:	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
Am TÜV 1, 45307 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 additional requirements of the Regulation (EU) 2017/745, Article 120(3), in addition to the essential requirements and provisions of Council Directive 93/42/EEC.

Valid of this Declaration: 13.12.2019 - 26.05.2024

Daejeon, 11.10.2022

Place, Date of Issue: **An-Soo Ko, President**

Digitally signed by Ceaicovschi Tudor
Date: 2024.10.04 15:25:13 EEST
Reason: MoldSign Signature
Location: Moldova

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