

EC Declaration of Conformity

Manufacturer's name POTEC Co., Ltd.

Manufacturer's Address 40-4, Techno 2-ro, Yuseong-gu, Daejeon, 34015, Korea

SRN (Single Registration Number): -

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

Name of the device : Auto Lensmeter

Type designation(s): PLM-8000, PLM-8000PD

Intended purpose: Measurement of vertex powers, cylinder axis, prismatic power and prism base setting within a restricted area at a specified location of a lens

Basic UDI-DI: 88092400112SM

Classification: Class I (Rule 13 of Annex VIII, MDR)

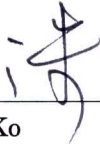
Standard : ISO 13485:2016, EN 60601-1:2006+ AC2010 + A1:2013,
EN 60601-1-2:2015, EN 60601-1-6:2010, EN ISO 14971:2012,
EN ISO15004-1:2009, EN ISO 15223-1:2016, EN 62304:2006,
EN 62366:2008, EN ISO 8598-1:2014

This declaration of conformity is issued under the sole responsibility of POTEC Co., Ltd. We hereby declare that the device specified above that is covered by the present declaration is in conformity with Regulation (EU) MDR 2017/745 and Directive 2011/65/EU. This declaration is supported by the Quality System approval to ISO 13485.

All supporting documentation is retained at the premises of the manufacturer.

Daejeon, 05.05.2021

Place, Date of Issue:


An-Soo Ko
President
POTEC Co.,Ltd.