POTEC Co., Ltd
40-4, Techno 2-ro, Yuseong-gu, Daejeon, 34015, Korea

TEL: +82-42-632-3536
FAX: +82-42-632-3537
URL : http://www.potec.biz

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 :	LCD Chart
Type designation(s):	PLC-8000, PLC-8000pola, TCP-4000, CV 600, TCP-4000P, CV 800P
Intended purpose;	It used to measure the subjective refractive power of the human eye (e.g. measuring visual acuity)
Basic UDI-DI:	88092400113SP
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, ISO 8596:2017, EN ISO 10938:2016

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, 28.04.2021

Place, Date of Issue:

An-Soo Ko
President
POTEC Co.,Ltd.