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
Manufacturer's SRN:	KR-MF-000012281
EC Authorized Representative:	MDSS GmbH Schiffgraben 41, 30175 Hannover, Germany
EC Authorized Representative's SRN	DE-AR-000005430
Name of the device:	LCD Chart
Type designation(s):	PLC-9000, PLC-9000pola
Intended Use:	LCD Chart displays acuity charts to measure subjective Refraction power of human eye (i.e. measuring visual acuity).
Basic UDI-DI:	88092400113SP
Classification:	Class I (Rule 13 of Annex VIII, MDR)
Conformity Assessment Procedure:	POTEC Co., Ltd. uses the following procedures for the CE-labeling of according the Regulation MDR 2017/745: Class I : EC conformity declaration according to Annex II + Annex III.
Standard:	EN ISO 13485:2016 + AC:2018 + A11:2021, EN 60601-1:2006 + A1:2013 + A2:2021, EN 60601-1-2:2015 + A1:2021, EN 60601-1-6:2010 + A2:2021, EN 62366-1:2015 + A1:2020, EN 62304:2006 + A1:2015, EN ISO 14971:2019 + A11:2021, EN ISO15004-1:2020, EN ISO 10938:2016, EN ISO 20417:2021, EN ISO 15223-1:2021
Common Specification (CS)	-

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.

POTEC CO., LTD.
40-4, Techno 2-ro Yuseong-gu,
Daejeon, 305-509, Korea
Tel : +82-42-632-3536 Fax : +82-42-632-3537

Daejeon, 20.01.2025
Place, Date of Issue:

An-Soo Ko
President
POTEC Co., Ltd.