

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 Chart Projector

Type designation(s): PACP-8000, TCP-4042, Rodachart 422

Intended purpose: Project chart used to measure the subjective refractive power of the human eye (e.g. measuring vision)

Basic UDI-DI: 88092400114SR

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


Standard : ISO 13485:2016, EN 60601-1:2006+ 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 Korea, 31.03.2021

Place, Date of Issue:


An-Soo Ko
President
POTEC Co.,Ltd.