



EU DECLARATION OF CONFORMITY for Visual Acuity Chart System

**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
concerning Medical Devices.**

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name: Visual Acuity Chart System

Legal Manufacturer:
(Name on Label) SCIENCETERA Co., Ltd.
B1602, 302, Galmachi-ro, Jungwon-gu, Seongnam-si
Gyeonggi-do 13201 Republic of Korea

Manufacturers SRN: KR-MF-000018391

Basic UDI-DI: 8800104TSLC2000SM

Variants: As per Appendix II (This document) - Product Listing/Schedule

Intended purpose: To display visual acuity test images on a screen for the purpose of patient's eyesight test

MDR Classification: Class I,
in accordance with MDR Annex VIII, Chapter III, Rule 13,
Part A - PRODUCTION QUALITY ASSURANCE

Notified Body: Not Applicable

Certificate: Not Applicable

EU Authorized Representative: Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar,
BKR 4013 Malta.

EU Authorized Representative SRN: MT-AR-000000234

Medical Device Regulation

Assessment Route: Issuing of the Declaration of Conformity in accordance with Article 19
after drawing up the technical documentation laid out in Annexes II and III
of the EU MDR 2017/745.

Date, place: 2026-06-26, Gyeonggi-do, Republic of Korea

Signature:

Eashin, Lee
Quality Representative - PRRC

Yongik, Cho
Chief Executive Officer - Top management

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I - Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

2017/745

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

ISO 13485:2016

Medical devices — Quality management systems — Requirements for regulatory purposes

ISO 14971:2019

Medical devices — Application of risk management to medical devices

ISO 15223-1:2021

Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

ISO 20417:2021

Medical devices — Information to be supplied by the manufacturer

ISO 15004-1:2020

Ophthalmic instruments — Fundamental requirements and test methods

IEC 60601-1:2005+A1:2012+A2:2020

Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014+A1:2020

Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-1-6:2010+A1:2013+A2:2020

Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability

IEC 62366-1:2015+A1:2020

Medical devices — Part 1: Application of usability engineering to medical devices

IEC 62304:2006+A1:2015

Medical device software — Software life cycle processes

ISO 8596:2017

Ophthalmic optics — Visual acuity testing — Standard and clinical optotypes and their presentation

Appendix II - Product Listing/Schedule

Catalogue Number

UDI-DI	Device Name	EMDN Code
TSLC-2000 08800104100024	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHER
TSLC-2000P 08800104100093	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHER
LC-R1 08809909320309	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHER
GLC-3000A 08800104100109	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHER
GLC-3000AP 08800104100116	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHER
HDC-100 08809909320033	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHER
LUCID-LC 08809909320309	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHER
VA-1 08809909320026	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHER

Version history

Version	Compiled by	Date	Description
1.0	Eashin, Lee / PRRC	2025-09-26	Initial issue
1.1	Eashin, Lee / PRRC	2026-06-26	The EU Declaration of Conformity has been revised to align the Basic UDI-DI with the EUDAMED registration information. There are no changes to the device design, intended purpose, risk class, or conformity assessment route.