



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

Manufacturers SRN: KR-MF-000018391

Basic UDI-DI: 88001041TSLC2000LE

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

EC 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: September 26, 2025, 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+AMD1:2012+AMD2:2020**

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

## **IEC 60601-1-2:2005+AMD1:2020**

*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+AMD1:2013+AMD2:2020**

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

## **IEC 62366-1:2015+AMD1:2020**

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

## **IEC 62304:2006+AMD1:2015**

*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 - OTHERS
TSLC-2000P 08800104100093	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHERS
LC-R1 08809909320309	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHERS
LC-R1P 08809909320319	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHERS
GLC-3000A 08800104100109	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHERS
GLC-3000AP 08800104100116	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHERS
HDC-100 08809909320033	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHERS
LUCID-LC 08809909320309	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHERS
VA-1 08809909320026	Visual Acuity Chart System	Q0299, OPHTHALMIC DEVICES - OTHERS

## Version history

Version	Compiled by	Date	Description
1.0	Eashin, Lee / PRRC	September 26, 2025	Initial