



SCIENCETERA

TSC-DoC-002

EU DECLARATION OF CONFORMITY for Digital Refractor

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

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

SCIENCETERA Co., Ltd. hereby declares that the medical device identified in this declaration conforms to Regulation (EU) 2017/745 on medical devices.

General Product Name: Digital Refractor

Legal Manufacturer:
(Name on Label) SCIENCETERA Co., Ltd.
B 1602, 302, Galmachi-ro, Jungwon-gu, Seongnam-si
Gyeonggi-do 13201 Republic of Korea

Manufacturer's SRN: KR-MF-000018391

Basic UDI-DI: 88001041TSDR3000NJ

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

Intended purpose: The Digital Refractor is intended to be used by trained eye-care professionals for subjective refraction and binocular vision assessment by presenting various optical lens combinations and test conditions to support the determination of refractive correction.

MDR Classification: Class I,
in accordance with Annex VIII, Rule 13 of Regulation (EU) 2017/745.

Notified Body: Not Applicable

EU Certificate: Not Applicable

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

EU Authorized Representative's 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: July 14, 2026, Gyeonggi-do, Republic of Korea

Signature:

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

The following standards and technical specifications have been applied, in whole or in part, as documented in the technical documentation:

Regulation (EU) 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 10993-1:2018

Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

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 10341:2012

Ophthalmic instruments — Refractor heads

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 60601-1-2:2014+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

Appendix II - Product Listing/Schedule

Catalogue Number

UDI-DI	Device Name	EMDN Code
TSDR-3000 08800104100079	Digital Refractor	Z12120115, OPTOMETERS
DR-R1 08800104100123	Digital Refractor	Z12120115, OPTOMETERS
GDR-3100 08800104100130	Digital Refractor	Z12120115, OPTOMETERS
DAV-31P 08800104100147	Digital Refractor	Z12120115, OPTOMETERS
DR-1 08800104100154	Digital Refractor	Z12120115, OPTOMETERS

Version history

Version	Compiled by	Date	Description
1.0	Eashin, Lee / PRRC	July 14, 2026	Initial issue