

# CERTIFICATE OF ACCREDITATION

**Finemedix Co., Ltd.**

Accreditation No. : KT1123

Corporation Registration No. : 170111-0383357

Address of Laboratory : (Branch site)140-9 Yuram-ro, Dong-gu, Daegu, Republic of Korea

Date of Initial Accreditation : August 03, 2023

Validity of Accreditation : August 03, 2023 ~ August 02, 2027

Scope of Accreditation : Attached Annex

Date of issue : August 03, 2023

This testing laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to Joint ISO-ILAC-IAF Communiqué).



*CHIN CHONGWOOK*

**Head**

**Korea Laboratory Accreditation Scheme**

# Korea Laboratory Accreditation Scheme

No. KT1123

## 09. Biological Testing

### 09.002 Microorganisms

Test method	Materials/ Products	Standard designation	Test range	Site	Field testing
ISO 11737-1:2018/Amd 1:2021	Microorganisms	Sterilization of health care products - Microbiological methods - part 1: Determination of a population of microorganisms on products AMENDMENT1 (Membrane filtration, Spread plating)	more than 0 CFU/unit	BS	N
ISO 11737-2:2019	Microorganisms	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (Membrane filtration, Direct immersion)	qualitative analysis (positive/negative)	BS	N
MFDS Notice No.2023-2 (01.12.2023.)	Microorganisms	Korean Pharmacopoeia 12th ed. [Asterisk5] Article 2 5. General test 13. Microbiological examination of nonsterile products: Microbial enumeration tests (Membrane filtration, Plate-count)	more than 0 CFU/g or more than 0 CFU/mL	BS	N
MFDS Notice No.2023-2 (01.12.2023.)	Microorganisms	Korean Pharmacopoeia 12th ed. [Asterisk5] Article 2 5. General test 12. Sterility test (Membrane filtration, Direct immersion)	qualitative analysis (positive/negative)	BS	N

End.