

CERTIFICATE OF ACCREDITATION

QnAGMP

Accreditation No. : KT676

Corporation Registration No. : 134111-0412910

Address of (Branch site) 2801 ~ 2812, A-Dong, Anyang IS BIZ Tower Central
Laboratory : 25, Deokcheon-ro 152beon-gil, Manan-gu, Anyang-si, Gyeonggi-do, Republic of Korea

Date of Initial Accreditation : October 26, 2015

Validity of Accreditation : October 26, 2023 ~ October 25, 2027

Scope of Accreditation : Attached Annex

Date of issue : October 18, 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. KT676

02. Chemical Testing

02.012 Gases

Test method	Materials/ Products	Standard designation	Test range	Site	Field testing
ISO 10993-7:2008/ Amd 1:2019	Gases	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals 4.4.6.3 Exhaustive extraction	Ethylene oxide : (0.1 ~ 10.0) mg/device Ethylene chlorohydrin : (0.1 ~ 10.0) mg/device Ethylene glycol : (5 ~ 200) mg/device	BS	N
KS P ISO 10993-7:2008	Gases	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals 4.4.6.3 Exhaustive extraction	Ethylene oxide : (0.1 ~ 10.0) mg/device Ethylene chlorohydrin : (0.1 ~ 10.0) mg/device Ethylene glycol : (5 ~ 200) mg/device	BS	N

Korea Laboratory Accreditation Scheme

No. KT676

09. Biological Testing

09.002 Microorganisms

Test method	Materials/ Products	Standard designation	Test range	Site	Field testing
European Pharmacopoeia 11th edition (2023)	Microorganisms	2.6 BIOLOGICAL TESTS 2.6.1 Sterility [Exception] Catgut and other surgical sutures	Qualitative analysis (Visual inspection)	BS	N
European Pharmacopoeia 11th edition (2023)	Microorganisms	2.6 BIOLOGICAL TESTS 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests	more than 0 CFU/g or more than 0 CFU/mL	BS	N
ISO 11737-1:2018	Microorganisms	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	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	Qualitative analysis (Visual inspection)	BS	N
USP-NF 2023	Microorganisms	<61> Microbiological examination of nonsterile products: Microbial enumeration test	more than 0 CFU/g or more than 0 CFU/mL	BS	N
MFDS Notice No.2023-40 (06.09.2023.)	Microorganisms	Korean Pharmacopoeia 12th ed. [Arterisk5] Article 2 5. General test 12. Sterility test	Qualitative analysis (Visual inspection)	BS	N
MFDS Notice No.2023-40 (06.09.2023.)	Microorganisms	Korean Pharmacopoeia 12th ed. [Arterisk5] Article 2 5. General test 13. Microbiological examination of non-sterile products: Microbial enumeration tests	more than 0 CFU/g or more than 0 CFU/mL	BS	N

End.