



Management System Certification Body No. MSCB-105

CERTIFICATE

No. 24-B-0908 Rev. 0

W.L. MED Co., Ltd.

**246, Geumwangosan-ro, Geumwang-myeon, Anseong-si,
Gyeonggi-do, Republic of Korea**

Company Reg. No.: 125-86-13884

has documented and implemented system in compliance with the requirements of

ISO 13485:2016

Medical Devices Quality Management System

for

**Design & Development, Production, E.O gas sterilization
and Sales of Pen Needle, Syringe, Cannula**

Technical Area:

A: Non-active Medical Devices - General non-active, non-implantable medical devices,

D: Sterilization Method for Medical Devices - Ethylene oxide gas sterilization (EOG)

The certificate is issued on the basis of the results mentioned in the pertinent audit report.
Validity of the certificate is conditionally limited by positive results of surveillance audits, which the certified company is committed to undergo.

This certificate can be invalid if the certificate holder does not fulfill the conditions set out in the certification agreement.

(Exclusions : Clause 7.5.3 / 7.5.4 / 7.5.9.2 / 7.5.10)

Initial issue date: May. 18. 2021
Re-issue date: Apr. 26. 2024
Expire date: May. 17. 2027



G. Gilbert
G. Gilbert

Head of Certification Body





Management System Certification Body No. MSCB-105

의료기기-품질경영시스템인증서

No. 24-B-0908 Rev. 0

(주)웰라이프메드

경기도 안성시 금광면 금광오산로 246

사업자등록번호: 125-86-13884

하기 규격에 따라 의료기기-품질경영시스템이

적격하게 수립 및 유지됨을 확인함

ISO 13485:2016

인증범위

Pen Needle, Syringe, Cannula 의

설계, 개발, 생산, E.O 가스 멸균, 판매

Technical Area:

- A: Non-active Medical Devices - General non-active, non-implantable medical devices,**
- D: Sterilization Method for Medical Devices - Ethylene oxide gas sterilization (EOG)**

본 인증서는 적합한 심사결과에 근거하여 발행되었으며, 인증서의 유효성은 정해진 주기에 따른 사후심사의 긍정적인 결과를 조건으로 유지 됨.

인증표준계약에 따라 상기 인증주체의 의무를 이행하지 않을 경우 인증서의 유효성은 무효가 될 수 있음.

(Exclusions : Clause 7.5.3 / 7.5.4 / 7.5.9.2 / 7.5.10)

최초 발행일: 2021. 05. 18

재발행일: 2024. 04. 26

만료일: 2027. 05. 17



G. Gilbert

G. Gilbert

Head of Certification Body

