Global Inter Certification

Management System Certification Body No.MSCB-108

CERTIFICATE

No. 24-B-0513 Rev.0

This is to certify that the Medical Devices-Quality Management Systems of

OMNIC&S Inc.

301, 302, 288, Digital-ro, Guro-gu, Seoul, Republic of Korea
[LAXTHA Inc.(OEM)] 4th floor, 106, Techno 2-ro, Yuseong-gu, Daejeon, Republic of Korea

Company Reg. No.: 113-86-82660

has documented and implemented system in compliance with the requirements of

ISO 13485:2016
Medical Devices-Quality Management Systems

for

Design & Development, Production and Sales of Products "Monitoring devices"

Technical Area:
Active Medical Devices (Non-Implantable) - Monitoring devices

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.

ISO 13485 CERTIFIED

ACCREDITED Management Systems Certification Body MSCB 108

Initial issue date: Nov. 15. 2024
Expire date: Nov. 14. 2027

Tyrone Dyse
Head of Certification Body

450 North Brand Boulevard. Suite 600 - #6007 Glendale, Ca. 91203 U.S.A.
http://www.gicert.org/

Global Inter Certification

Management System Certification Body No.MSCB-108

의료기기품질경영시스템인증서

No. 24-B-0513 Rev.0

㈜옴니씨앤에스

서울특별시 구로구 디지털로 288, 3 층 301 호, 302 호(구로동, 대륭포스트타워 1)
[(주)락싸(OEM)] 대전광역시 유성구 테크노 2 로 106 ,4 층

사업자등록번호: 113-86-82660

하기 규격에 따라 의료기기 품질경영시스템이 적격하게 수립 및 유지됨을 확인함

ISO 13485:2016

인증범위

"Monitoring devices" 설계 및 개발, 제품 생산 및 판매

Technical Area:
Active Medical Devices (Non-Implantable) - Monitoring devices

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.

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최초 발행일: 2024. 11. 15
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