Certificate of Registration

Certificate No. **CE/KOR/2019/06/21**

Issued To: **Lunit Inc**
15 Floor
27 Teheran-ro 2-gil
Gangnam-gu
Seoul, 06241
Republic of Korea

Legal Manufacturer [SRN: Not yet available]

Issued By: **Advena Limited**
Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta.

EC-REP [SRN: MT-AR-000000234]

EU Competent Authority: **Malta Medicines Authority (MMA)**
Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000
Malta.
Tel: +356 2343 9000
Email: info.medicinesauthority@gov.mt

We hereby declare that:

- Device registrations for the medical devices mentioned within this certificate have duly been completed with an EU Competent Authority.
- Due to the 26th May 2021 Date of Application of Regulation (EU) 2017/745 (MDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 93/42/EEC (MDD) through Article 120 (3) of Regulation (EU) 2017/745 is legitimately permitted.
- Due to the 26th May 2022 Date of Application of Regulation (EU) 2017/746 (IVDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 98/79/EC (IVDD) through Article 110(3) of Regulation (EU) 2017/746 is legitimately permitted.

Anthony Kirby – Managing Director (Malta)

Date of Issue: 1 July 2021 **AR Cover Begins:** 01 August 2021 **AR Cover Ends:** 31 July 2022

This certificate is subject to the organisation maintaining their documentation in compliance with the EU legislation as indicated in this certificate.

This certificate is for the exclusive use of Advena Ltd's clients and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

Appendix A

Product Details, Names or Trade Names	EU Legislation	Classification	Device Registration Reference(s)
Lunit INSIGHT CXR	MDD	Class I	DVC-MT-19-11-000290

Declaration of Conformity

for Lunit INSIGHT CXR

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Lunit INSIGHT CXR
Legal Manufacturer: (Name on Label)	Lunit Inc. 15 Floor, 27 Teheran-ro 2-gil, Gangnam-gu, Seoul, 06241, Republic of Korea
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Computer-Assisted Detection (CADe) software intended to aid interpreting physicians in detecting, localizing, identifying, and characterizing suspicious abnormal radiologic findings in chest radiographs.
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name Jungin Lee **Position** QMR of Lunit Inc.

Signed DocuSigned by: Jungin Lee 00F2EB5E50594D8... **Date** 2021-03-16

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

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
Council Directive 93/42/EEC	European Medical Devices Directive 93/42/EEC including amendments by 2007/47/EC
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes (IEC 62304:2006)
EN 62366:2008	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)
IEC 62366-1:2015	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
IEC 62366-2:2016(en)	Medical Devices - Part 2: Guidance on the application of usability engineering to medical devices
IEC/TR 80002-1:2009	Medical Device Software - Part 1: Guidance on the application of ISO 14971 to medical device software
IEC 82304-1:2016	Health software — Part 1: General requirements for product safety
MEDDEV 2.1/6	Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices
MEDDEV 2.7/1 rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
MEDDEV 2.12/1 rev.8	Guidelines on a Medical Devices Vigilance System
MEDDEV 2.12/2 rev.2	Post Market Clinical Follow-up studies

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
113012	Lunit INSIGHT CXR	63386
113015	Thoracic Care Suite with Lunit INSIGHT CXR	63386
113016	REiLI with Lunit INSIGHT CXR	63386

Version History

Version	Compiled by	Date	Description
1.0	Hyungtak Harry Han	22/10/2019	First issue
2.0	Hyungtak Harry Han	09/04/2020	Change of manufacturing site address
3.0	Hyungtak Harry Han	02/07/2020	Inclusion of part numbers, GMDN code; Updated standards; Address arrangement change (equivalent manufacturing site) Corrected intended use
4.0	Hyungtak Harry Han	15/03/2021	Updated applicable standards in accordance with EN Harmonized Standards Inclusion of variants: - Thoracic Care Suite with Lunit INSIGHT CXR (113015) - REiLI with Lunit INSIGHT CXR (113016)

Certificate of Designation

Client Ref. **KOR/2019/06/21**

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15 Floor
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Malta.
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In accordance with the Mandate executed by both the Legal Manufacturer and Advena Limited, this Certificate of Designation is issued and confirms the period of representation. Furthermore, this certificate confirms the medical devices Advena Limited acts as EU Authorised Representative for the Legal Manufacturer.

The devices listed in Appendix A must indicate Advena Ltd as the EU Authorised Representative, and in the following format, as applicable to EU legislation:

EC REP

Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Anthony Kirby – Managing Director (Malta)

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Appendix A

Product Details, Names or Trade Names	EU Legislation	Classification	Date of Declaration
Lunit INSIGHT CXR	MDD	Class I	16/03/2021

문서확인번호 : SE1B-YAZJ-MQG4-NEC1

제허 20-896 호

의료기기 제조 허가증

(업 허가번호 : 제 6126 호)

구 분	[✔] 제조 / [ ] 수입	[✔] 품목 / [ ] 품목류	
명 칭 (제품명, 품목명, 모델명)	Lunit INSIGHT CXR (v3.1.2.X),2등급의료영상검출·진단보조소프트웨어,Lunit INSIGHT CXR	분류번호(등급)	E11030.01 (2)
모 양 및 구 조	별첨		
원 재 료	별첨		
제 조 방 법	기 허가사항과 동일		
성 능	별첨		
사 용 목 적	기 허가사항과 동일		
사 용 방 법	별첨		
사용 시 주의사항	기 허가사항과 동일		
포 장 단 위	기 허가사항과 동일		
저장방법 및 사용기간	저장방법 : 기 허가사항과 동일, 사용기간 : 기 허가사항과 동일		
시 험 규 격	기 허가사항과 동일		
제조(수입)업자 정보	제조(수입)업자 : (주)루닛, 서울특별시 강남구 테헤란로2길 27 15층 (역삼동, 비젼타워) 제조원 : 상동		
허 가 조 건	없음		
유 효 기 간	2020.10.19 ~ 2025.10.18		
소 재 지	서울특별시 강남구 테헤란로2길 27 15층 (역삼동, 비젼타워)		
비 고	[√] 기술문서 심사 [ ] 임상자료 심사		

「의료기기법」 제6조 · 제15조 및 같은 법 시행규칙 제5조제2항 · 제34조에 따라 위와 같이 허가합니다.

2021 년 03 월 23 일

식 품 의 약 품 안 전 처 장 (인)
직 인 생 략