

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 731765 R000

Manufacturer: Lunit Inc.

Address:

4-8 F,
374, Gangnam-daero,
Gangnam-gu,
Seoul
06241
Republic of Korea

Single Registration Number: KR-MF-000005200

EU Authorised Representative: MT Promedt Consulting GmbH

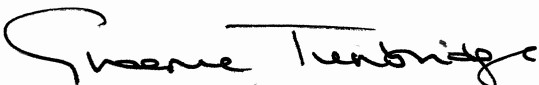
Address:

Ernst-Heckel-Straße 7
66386 St. Ingbert
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-10-31**

Current Issue Date: **2022-12-07**

Starting Validity Date: **2022-12-07**

Expiry Date: **2027-10-30**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS – MEDICAL DEVICE SOFTWARE	Class IIa



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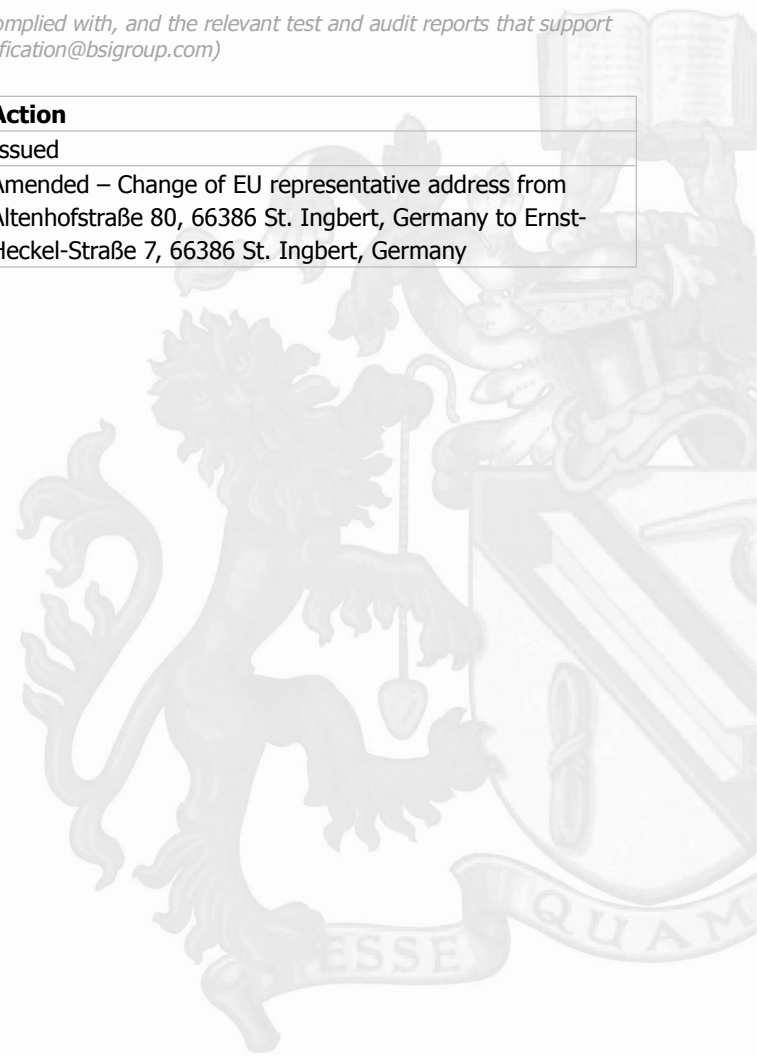
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-10-31	3252071	Issued
Current	3816146	Amended – Change of EU representative address from Altenhofstraße 80, 66386 St. Ingbert, Germany to Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.