

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

GE ULTRASOUND KOREA, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu
SEONGNAM-SI, GYEONGGI-DO
Republic of Korea

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-03-17
Certificate Registration No.: SX 60146260 0001
An audit was performed. Report No.: 32090188 001
This Certificate is valid until: 2021-11-04

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-03-17



Balazs Bozsik

Balazs Bozsik

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60146260 0001
Report No.: 32090188 001

Organization: GE ULTRASOUND KOREA, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu
SEONGNAM-SI, GYEONGGI-DO
Republic of Korea

Scope: Design and Development, Manufacture and Final Test of
Ultrasound Diagnostic Devices and Systems

Site Included:
GE Ultrasound Korea, Ltd.
65-1, Sangdaewon-dong, Jungwon-gu
Seongnami-si, Gyeonggi-do
462-120 Republic of Korea

Design and Development, Manufacture and Final Test of
Ultrasound Diagnostic Devices and Systems

Certification Body



Balk Balazs

Date: 2020-03-17

Balazs Bozsik