

EC Certificate

EU Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter 1,
Section 2 and 3 and Chapter III



Registration No.: HZ 2004702-01

Manufacturer: **GE Ultrasound Korea, Ltd.**
9, Sunhwan-ro 214beon-gil,
Jungwon-gu, Seongnam-si, Gyeonggi-do 13204
Republic of Korea

EUDAMED Single
Registration No.: No registration number available yet

Products: Class IIa - Z110401 ULTRASOUND SCANNERS

Authorised
representative(s): GE Medical Systems SCS
283 Rue de la Minière, 78530 BUC
France

Certificate history		
Revision:	Description:	Issue date:
0	Initial Version	2021-01-19

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.