Benannt durch Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 076726 0012 Rev. 00

Manufacturer:

SAMSUNG MEDISON CO., LTD.
3366, Hanseo-ro, Nam-myeon
Hongcheon-gun
Gangwon-do 25108
REPUBLIC OF KOREA

Authorized Representative:

Samsung Electronics GmbH
Am Kronberger Hang 6, 65824 Schwalbach am Taunus,
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.:   74956580

Valid from: 2020-07-06
Valid until: 2025-07-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-07-06

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(Class IIa and Class IIb Devices)

No. G10 076726 0012 Rev. 00

Device Group:	Z110401 - ULTRASOUND SCANNERS
Classification:	IIa
Intended Purpose:	-/-

The validity of this certificate depends on conditions and/or is limited to the following: None

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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