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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 076726 0011 Rev. 00

Manufacturer:

SAMSUNG MEDISON CO., LTD.

3366, Hanseo-ro, Nam-myeon

Hongcheon-gun

Gangwon-do 25108

REPUBLIC OF KOREA

**Product Category(ies): Ultrasonic Diagnostic Apparatus and PACS
(Picture Archiving and Communication System)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

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Valid from:

2019-08-26

Valid until:

2024-05-26

Date,

2019-08-26

Stefan Preiß

Head of Certification/Notified Body

EC Certificate

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Facility(ies):

SAMSUNG MEDISON CO., LTD.

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