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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.: 74954671

Valid from: 2019-08-26
Valid until: 2024-05-26

Date, 2019-08-26

Stefan Preiß
Head of Certification/Notified Body

Digitally signed by Bolocan Vladimir
Date: 2019.10.18 08:54:35 EEST
Reason: MoldSign Signature
Location: Moldova

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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Facility(ies):

SAMSUNG MEDISON CO., LTD.
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25108, REPUBLIC OF KOREA

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SAMSUNG MEDISON CO., LTD.
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