





Product Service

Certificate

No. Q5 092136 0005 Rev. 00

Holder of Certificate: Furuno Electric Co., Ltd.

System Products Division

2-20 Nishinomiyahama Nishinomiya, Hyogo 662-0934 JAPAN

Certification Mark:



Scope of Certificate: Design and Development, Production and

Distribution of In Vitro Diagnostic Chemical Analyzers and Ultrasound Bone Densitometers. Production and Distribution of Maintenance Parts for In Vitro Diagnostic Chemical Analyzers. Distribution of Cleaning Solutions and Consumable Supplies for In Vitro Diagnostic Chemical Analyzers.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: JA1417583

Valid from: 2020-07-01 Valid until: 2021-03-31

Date, 2020-06-23 Christoph Dicks

Head of Certification/Notified Body





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Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016)

DIN EN ISO 13485:2016

Facility(ies): Furuno Electric Co., Ltd. FURUNO INT Center

2-20 Nishinomiyahama, Nishinomiya, Hyogo, 662-0934

JAPAN

Furuno Electric Co., Ltd. Headquarters

9-52 Ashihara-cho, Nishinomiya, Hyogo, 662-8580

JAPAN

Furuno Electric Co., Ltd. ME Nishinomiyahama Factory 2-35-1 Nishinomiyahama, Nishinomiya, Hyogo, 662-0934

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