



# Certificate

No. Q5 054475 0315 Rev. 02

Holder of Certificate:



**Rion Co., Ltd.**

3-20-41, Higashimotomachi, Kokubunji-shi  
Tokyo  
185-8533 JAPAN

Certification Mark:



Scope of Certificate:

**Design and Development, Production,  
Distribution and Servicing of Hearing Aids,  
Audiometers, Eustachian Tube Function  
Testing Equipment and Electro Gustometer.**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 054475 0315 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_054475_0315_Rev._02)

Report No.:

**JA1606046**

Valid from:

**2021-08-10**

Valid until:

**2023-03-31**

Date, **2021-08-10**

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):**

**Rion Co., Ltd.**  
**3-20-41, Higashimotomachi, Kokubunji-shi, Tokyo,**  
**185-8533 JAPAN**

Design and Development, Production, Distribution and Servicing of  
Hearing Aids, Audiometers, Eustachian Tube Function Testing  
Equipment and Electro Gustometer

**Rion Co., Ltd. Tokyo Sales Office**  
**2-5-5, Yoyogi, Shibuya-ku, Tokyo, 151-0053 JAPAN**

Distribution of Hearing Aids and Audiometers

**Rion Co., Ltd. Nishi-Nihon Sales Office**  
**2-5-5, Umeda, Kita-ku, Osaka-shi, Osaka, 530-0001**  
**JAPAN**

Distribution of Hearing Aids and Audiometers

**Rion Co., Ltd. Sendai Sales Office**  
**25-13, Minami-Onoda, Taihaku-ku, Sendai-shi, Miyagi,**  
**982-0015 JAPAN**

Distribution of Hearing Aids and Audiometers

**Rion Co., Ltd. Rionet Center**  
**2-1-5, Yoyogi, Shibuya-ku, Tokyo, 151-0053 JAPAN**

Distribution and Servicing of Hearing Aids

**Rion Techno Co., Ltd.**  
**2-22-2, Hyoe, Hachioji-shi, Tokyo, 192-0918 JAPAN**

Production, Distribution and Servicing of Hearing Aids

**Rion Service Center Co., Ltd.**  
**2-22-2, Hyoe, Hachioji-shi, Tokyo, 192-0918 JAPAN**

Servicing of Audiometers

**Rion Service Center Co., Ltd. Tohoku Office**  
**25-13, Minami-Onoda, Taihaku-ku, Sendai-shi, Miyagi,**  
**982-0015 JAPAN**

Servicing of Audiometers



Product Service

# Certificate

No. Q5 054475 0315 Rev. 02

**Kyushu Rion Co., Ltd.**  
**5-18, Reisenmachi, Hakata-ku, Fukuoka-shi, Fukuoka,**  
**812-0039 JAPAN**

Production, Distribution and Servicing of Hearing Aids  
Distribution and Servicing of Audiometers

**Kyushu Rion Co., Ltd. Rionet Center Hakata**  
**5-22, Tenyamachi, Hakata-ku, Fukuoka-shi, Fukuoka,**  
**812-0025 JAPAN**

Distribution and Servicing of Hearing Aids

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