



Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

Alere Medical Co., Ltd
357 Matsuhidai, Matsudo-shi,
Chiba-ken 270-2214,
Japan

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

ISO 13485:2003
EN ISO 13485:2012

The Quality Management System is applicable to:

**Design, development and manufacture of in vitro diagnostic
tests. Import and supply of in vitro diagnostic tests,
instruments and medical devices for domestic sales.**

This certificate is valid only in association with the certificate schedule bearing the same
number on which the locations applicable to this approval are listed.


This certificate forms part of the approval identified by certificate number LRQ 4005076

Approval
Certificate No: LRQ 4005076/A

Original Approval: 18 March 2009

Current Certificate: 18 March 2015

Certificate Expiry: 17 March 2018


Issued by: Lloyd's Register Quality Assurance Limited



001

Hiramford, Middlemarch Office Village, Siskin Drive, Coventry, CV3 4FJ, United Kingdom.



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CERTIFICATE SCHEDULE

Alere Medical Co., Ltd
357 Matsuhidai, Matsudo-shi,
Chiba-ken 270-2214,
Japan

Head Office

7F Shinjuku NS Building,
2-4-1 Nishi-Shinjuku, Shinjuku-ku
Tokyo 163-0807
Japan

Activities

Business development of in vitro
diagnostic tests, instruments and medical
devices.

Locations

Chiba Plant,
357 Matsuhidai, Matsudo-shi,
Chiba-ken 270-2214
Japan

Activities

Design, development and manufacture of
in vitro diagnostic tests.

Chiba Logistics Center,
336-17 Matsuhidai, Matsudo-shi,
Chiba-ken 270-2214
Japan

Packaging, storage and distribution of in
vitro diagnostic tests, instruments and
medical devices.

Approval
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Original Approval: 18 March 2009

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Hiramford, Middlemarch Office Village, Siskin Drive, Coventry, CV3 4FJ, United Kingdom.



Registration NO. 4514

NOTARIAL CERTIFICATE

This is to certify that as a result of checking the attached copy of document with its original, I have found that the copy exactly corresponds with the original.

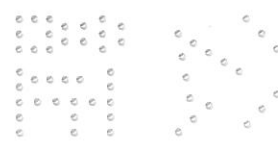
Dated this 8th day of December, 2015.

YOSHITERU KAWAMURA

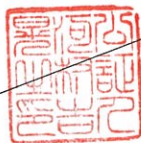
NOTARY



№ 063804



囑託人櫻井健の提出した別添文書の写しはその原本と対照し符合することを認めた。



よって、これを認証する。

平成27年 12 月 8 日、本公証人役場において

東京都千代田区内幸町2丁目2番2号
東京法務局所属

公 証 人
Notary

河 本 亮



YOSHITERU KAWAMURA

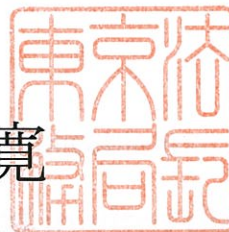
証 明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、
真実のものであることを証明する。

平成27年 12 月 8 日

東京法務局長

加藤朋寛



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
This public document
2. has been signed by YOSHITERU KAWAMURA
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of YOSHITERU KAWAMURA, NOTARY
Certified
5. at Tokyo
6. December 8, 2015
7. by the Ministry of Foreign Affairs
8. 15-**№ 063804**
9. Seal/stamp:
10. Signature



A. Ogawa

Ayako OGAWA

For the Minister for Foreign Affairs