

# ISO 13485

## Management System Certificate

Certificate Number : JQA-MD0029

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Organization :

**NISSUI PHARMACEUTICAL CO., LTD.**

24-6 UENO 3-CHOME, TAITO-KU, TOKYO, JAPAN



**ISO 13485**



MS  
CM009

JQA certifies that the above organization operates the Quality Management System, within the scope of the Appendix attached, which has been assessed and found to comply with the requirements of,

**ISO 13485:2016 / JIS Q 13485 :2018**

Registration Date : October 31, 2008

Last Renewal Date : October 31, 2020

Expiry Date : October 30, 2023

Feel free to contact JQA for the validity of this certificate.

A handwritten signature in black ink, reading 'N. Kobayashi'.

**NORIAKI KOBAYASHI**  
PRESIDENT

1-25 KANDASUDACHO, CHIYODA-KU, TOKYO, JAPAN

**JAPAN QUALITY ASSURANCE ORGANIZATION**

To be used in conjunction with attached Appendix.

The logo for JQA, consisting of the letters 'JQA' in a bold, blue, sans-serif font.

# ISO 13485

## Appendix

Certificate Number : JQA-MD0029

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Organization :

NISSUI PHARMACEUTICAL CO., LTD.

Scope of Registration:

- THE DESIGN / DEVELOPMENT, MANUFACTURE AND SALES OF IN VITRO DIAGNOSTICS\*2 (REAGENT FOR IMMUNOLOGICAL TEST\*1, REAGENT FOR BACTERIOLOGICAL TEST\*1, REAGENT FOR HEMATOLOGICAL TEST, REAGENT FOR BIOCHEMICAL TEST AND REAGENT FOR ENDOCRINE TEST)
- THE MANUFACTURE AND SALES OF BULK REAGENTS FOR THE ABOVE-MENTIONED IN VITRO DIAGNOSTICS
- THE DESIGN / DEVELOPMENT, SALES, INSTALLATION AND SERVICING (REPAIR, MAINTENANCE, INSPECTION AND SUPPLY OF PARTS) OF FLUORESCENT IMMUNOASSAY ANALYZERS\*2, MICROBIAL IDENTIFICATION\*2 AND ANTIMICROBIAL SUSCEPTIBILITY ANALYZERS\*2
- THE MANUFACTURE (PACKAGING, LABELLING AND STORAGE) AND SALES OF MICRO TITER PLATE READER

\*1 INCLUDES IN VITRO DIAGNOSTICS WHICH CORRESPONDS TO CLASS III IN PMD ACT (JAPAN LAW NO. 145, 1960)

\*2 EXCEPT INTRODUCED PRODUCTS

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NORIAKI KOBAYASHI  
PRESIDENT

JAPAN QUALITY ASSURANCE ORGANIZATION

This Appendix is an integral part of the Certificate and should only be used in conjunction with the Certificate.



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## Appendix

Certificate Number : JQA-MD0029

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ASSOCIATED ORGANIZATION:

·YUKI PLANT

1075-2 HOKUNANMORO, YUKI-SHI, IBARAKI, JAPAN

[THE DESIGN / DEVELOPMENT AND MANUFACTURE OF IN VITRO DIAGNOSTICS\*2

(REAGENT FOR IMMUNOLOGICAL TEST\*1, REAGENT FOR BACTERIOLOGICAL TEST\*1,  
REAGENT FOR HEMATOLOGICAL TEST, REAGENT FOR BIOCHEMICAL TEST AND REAGENT  
FOR ENDOCRINE TEST)]

[THE MANUFACTURE OF BULK REAGENTS FOR THE ABOVE-MENTIONED IN VITRO  
DIAGNOSTICS]

[THE DESIGN / DEVELOPMENT, SALES, INSTALLATION AND SERVICING (REPAIR,  
MAINTENANCE, INSPECTION AND SUPPLY OF PARTS) OF FLUORESCENT IMMUNOASSAY  
ANALYZERS\*2, MICROBIAL IDENTIFICATION\*2 AND ANTIMICROBIAL SUSCEPTIBILITY  
ANALYZERS\*2]

[THE MANUFACTURE (PACKAGING, LABELLING AND STORAGE) OF MICRO TITER PLATE  
READER]

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