

Certificate JP10/040267

The management system of

NIPPON GENE CO., LTD.

SGS

Pharmaceutical Toyama Factory 1-1-22 Arakawa, Toyama-shi, Toyama-ken, 930-0982, Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

1. Design and manufacture of IVD for pregnancy testing, ovulation testing, infectious disease testing and immunodiagnostic testing
2. Design and manufacture of genetic analysis kit and control material for infectious disease

This certificate is valid from 25 October 2025 until 25 October 2028 and remains valid subject to satisfactory surveillance audits.

Issue 13. Certified since 25 October 2010

Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by

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Business Manager

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Certificate JP10/040267, continued

NIPPON GENE CO., LTD.

SGS

ISO 13485:2016

EN ISO 13485:2016

Issue 13

Sites

NIPPON GENE CO., LTD. Pharmaceutical Toyama Factory
1-1-22 Arakawa, Toyama-shi, Toyama-ken, 930-0982, Japan

1. Design and manufacture of IVD for pregnancy testing, ovulation testing, infectious disease testing and immunodiagnostic testing

NIPPON GENE CO., LTD. Diagnostics Office
2-7-18 Toiya-machi, Toyama-shi, Toyama-ken, 930-0834, Japan

1. Manufacture of IVD for pregnancy testing, ovulation testing, infectious disease testing and immunodiagnostic testing

2. Design and manufacture of genetic analysis kit and control material for infectious disease



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