

Certificate JP10/040267

The management system of

NIPPON GENE CO., LTD.

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

SGS

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 27 September 2023 until 25 October 2025 and remains valid subject to satisfactory surveillance audits.

Issue 12. Certified since 25 October 2010

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

Jonathan M. Hall

Authorised by

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Certificate JP10/040267, continued

NIPPON GENE CO., LTD.



ISO 13485:2016

EN ISO 13485:2016

Issue 12
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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