



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

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016



For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 25 October 2019 until 25 October 2022 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 21 October 2022
Issue 10. Certified since 25 October 2010

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by



0005

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

NIPPON GENE CO., LTD.

ISO 13485:2016 EN ISO 13485:2016



Issue 10

Detailed scope

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

Additional facilities

Diagnostics Office 2-7-18 Toiya-machi, Toyama-shi, Toyama-ken,
930-0834, Japan



0005