

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 13485:2003 EN ISO 13485:2012

For the following activities

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

This certificate is valid from 25 October 2016 until 31 March 2019 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 31 March 2019  
Issue 7. Certified since 25 October 2010

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

Authorised by

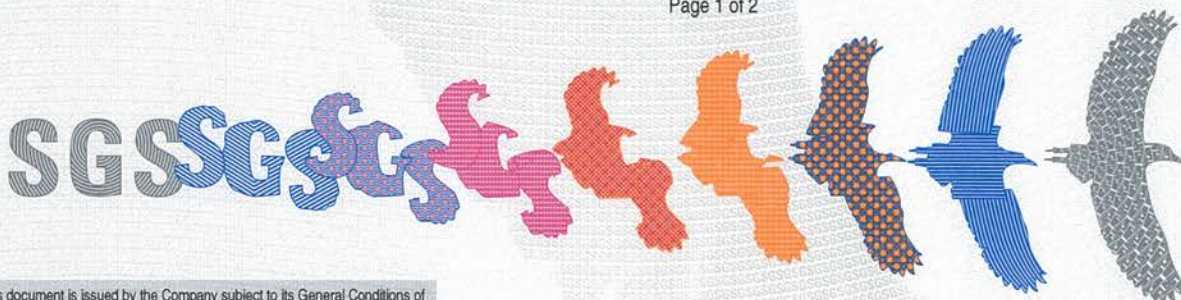


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