

# SGS

Certificate KR13/02010

The management system of

## Bioneer Corporation

(Head Office) 8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon, 34302  
Republic of Korea

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 30 September 2018 until 22 May 2019  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 29 April 2019  
Issue 4. Certified since 22 May 2013

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](http://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](http://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.

# Bioneer Corporation

## ISO 13485:2016 EN ISO 13485:2016



Issue 4

Detailed scope

**Design, Development, Manufacture and Distribution  
of In-Vitro Molecular Diagnostic Instruments**

**(Head Office) Design, Development and Manufacture  
of In-Vitro Molecular Diagnostic Instruments**

**(Pangyo R&D Center) Design, Development and Distribution  
of In-Vitro Molecular Diagnostic Instruments**

Additional facilities

**(Pangyo R&D Center) #702, Building B, Korea Bio Park, 700  
Daewangpangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13488  
Republic of Korea**



0005