Certificate KR13/02010

SCS

The management system of

Bioneer Corporation

Head Office: 8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon 306-220, Republic of Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

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

This certificate is valid from 22 May 2013 until 22 May 2016 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 29 April 2016

Issue 1. Certified since 22 May 2013

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

Authorised by



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

SGS 13485-2 0612 M2

Page 1 of 2







NAGEMENT SYSTEMS 005

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/Our-Company/Certified-Client-Directories/Certified-Client-Directories/Certified-Client-Directories/Certified-Client-Directories.aspx. 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



Certificate KR13/02010, continued

Bioneer Corporation

ISO 13485:2003 EN ISO 13485:2012



Issue 1

Detailed scope

Design, Development, Production and Distribution of In-Vitro Molecular Diagnostic Instruments;

Design, Development, Production and Distribution of In-Vitro Infectious Disease, Human Genetic, Cancer & Companion Molecular Diagnostic kits & Reagents.

Additional facilities

Pangyo R&D center : #702, Building B, Korea Bio Park, 700, Daewangpangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 463-400, Republic of Korea

Cheongwon(DNA/RNA prep kit's production) : 151-27, Namseok-ro, Nami-myeon, Cheongwongun, Chungcheongbuk-do, 363-813, Republic of Korea

