

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

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SGS 13485-2 0612 M2

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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



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