

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 13485:2003 EN ISO 13485:2012

For the following activities

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

This certificate is valid from 23 May 2016 until 31 March 2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 29 April 2019
Issue 3. 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
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SGS 13485-2 0614 M2

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Bioneer Corporation

ISO 13485:2003 EN ISO 13485:2012



Issue 3

Detailed scope

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

Additional facilities

Address of the Head Office

8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon 34302, Republic of Korea

Detailed scope for Head Office

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

Address of the Pangyo R&D center

#702, Building B, Korea Bio Park, 700, Daewangpangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13488, Republic of Korea

Detailed scope for Pangyo R&D center

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



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