

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
BIONEER Corporation
8-11, Munpyeongseo-ro
Daedeok-gu, Daejeon, 34302
Republic of Korea

has established and applies a quality management system for medical devices
for the following scope:

see attachment for scope and sites included

Proof has been furnished that the requirements specified in

EN ISO 13485:2012/AC:2012
EN ISO 13485:2012

are fulfilled. The quality management system is subject to yearly surveillance.


Effective Date: 2016-03-10
Certificate Registration No.: SX 60109139 0001
An audit was performed. Report No.: 21228249 002
This Certificate is valid until: 2018 10 31

Certification Body



Date 2016-03-10




Dipl.-Ing. C. Wiora

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60109139 0001
Report No.: 21228249 002

Organization: BIONEER Corporation
8-11, Munpyeongseo-ro
Daedeok-gu, Daejeon, 34302
Republic of Korea

Scope: Design and Development, manufacture and distribution of molecular diagnostic products used in the in-vitro diagnosis of infectious diseases, cancer and human genetics as well as reagents intended for purification of nucleic acids from human specimen

Certification Body



Date: 2016-03-10

Dipl.-Ing. C. Wiora

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Registration No.: SX 60109139 0001
Report No.: 21228249 002

Organization: BIONEER Corporation
8-11, Munpyeongseo-ro
Daedeok-gu, Daejeon, 34302
Republic of Korea

Scope:

Sites included:

Bioneer Corporation
Cheongwon 151-27, Namseok-ro, Seowon-gu, Cheongju-si,
Chungcheongbuk-do, 28182
Republic of Korea

Activities: Manufacture of reagents for purification of
nucleic acids from human specimen


Bioneer Corporation
B-702, Korea Bio Park Bldg, 700 Daewangpangyo-ro,
Bundang-gu, Seongnam-si,
Gyeonggi-do. 13488
Republic of Korea

Activities: Distribution

Certification Body



Date: 2016-03-10


Dipl.-Ing. C. Wiora