

**Business Stream Products
Certification Department**



TÜVRheinland®

LGA

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

BIONEER Corporation
Mr. EunSu Han
8-11, Munpyeongseo-ro
DAEDEOK-GU, DAEJEON, 34302
REPUBLIC OF KOREA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date October 30, 2018

Application for : QMS
Certificate No. : SX 60133285 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Mr. Han,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. SX 60133285 0001.

Kind regards

Certification body

M.Sc. M. Aihara

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

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 13485:2016


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

Effective Date: 2018-11-01
Certificate Registration No.: SX 60133285 0001
An audit was performed. Report No.: 21228249 008
This Certificate is valid until: 2021-08-03

Certification Body



Date 2018-10-30


M.Sc. M. Aihara

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 60133285 0001
Report No.: 21228249 008

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: 2018-10-30

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60133285 0001
Report No.: 21228249 008

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: 2018-10-30


M.Sc. M. Aihara