

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2134964-1
Certificate Holder: BIONEER Corporation
Bioneer Global Center, 71, Techno 2-ro, Yuseong-gu,
Daejeon, 34013 Republic of Korea

Scope: Design, Development, Manufacture and Distribution of molecular diagnostic reagents used in the in-vitro diagnosis of infectious diseases, cancer and human genetics, as well as disposable human specimen collection tubes and reagents intended for extraction of nucleic acids from human specimen.

Design, Development, Manufacture, Service and Distribution of molecular diagnostic instruments used in the In-vitro diagnosis of infectious diseases, cancer and human genetics

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 156159755-50
Effective date: 2024-08-04
Expiry date: 2027-08-03
Issue date: 2024-07-30
Replaces certificate SX 2134964-1 issued 2024-03-28

This certificate can be validated on <https://www.certipedia.com>

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o BIONEER Corporation Bioneer Global Center, 71, Techno 2-ro, Yuseong-gu, Daejeon, 34013 Republic of Korea	Design, Development, Manufacture and Distribution of in-vitro molecular diagnostic reagents used in the extraction of nucleic acids from human specimen. Manufacture and Distribution of molecular diagnostic reagents used in the in-vitro diagnosis of infectious diseases, cancer and human genetics. Design, Development, Manufacture and Distribution of disposable human specimen collection tubes. Design, Development, Manufacture, Service and Distribution of in-vitro molecular diagnostic instruments.
/02	c/o BIONEER Corporation 8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon, 34302 Republic of Korea	Design, Development and Manufacture of molecular diagnostic reagents used in the in-vitro diagnosis of infectious diseases, cancer and human genetics.
/03	c/o BIONEER Corporation B-702, Korea Bio Park Bldg, 700 Daewangpangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13488 Republic of Korea	Distribution (sales) of molecular diagnostic reagents used in the in-vitro diagnosis of infectious diseases, cancer and human genetics as well as reagents intended for extraction of nucleic acids from human specimen. Distribution (sales) of disposable human specimen collection tubes and in-vitro molecular diagnostic instruments.

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