

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

BIONEER Corporation  
Bioneer Global Center  
71, Techno 2-ro  
Yuseong-gu  
Daejeon  
34013  
Republic of Korea

Holds Certificate Number:

MD 821661

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, and distribution of in-vitro molecular diagnostic reagents used in the diagnosis of infectious diseases and human genetic testing.  
The design, development, manufacture, and distribution of in-vitro molecular diagnostic reagents used in the extraction of nucleic acids from human specimen.  
The design, development, manufacture, and distribution of saliva collection kit.  
The design, development, manufacture, distribution, and servicing of In-vitro molecular diagnostic instruments.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-05-15

Latest Revision Date: 2025-05-15

Effective Date: 2025-05-15

Expiry Date: 2028-05-14

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Certificate No: MD 821661

Location	Registered Activities
BIONEER Corporation Bioneer Global Center 71, Techno 2-ro Yuseong-gu Daejeon 34013 Republic of Korea	The design, development, manufacture, sales, and distribution of in-vitro molecular diagnostic reagents used in the diagnosis of infectious diseases. The design, development, manufacture, sales, and distribution of in-vitro molecular diagnostic reagents used in the extraction of nucleic acids from human specimen. The design, development, manufacture, sales, and distribution of saliva collection kit. The design, development, manufacture, distribution, sales, and servicing of In-vitro molecular diagnostic instruments.
BIONEER Corporation 8-11, Munpyeongseo-ro Daedeok-gu Daejeon 34302 Republic of Korea	The design, development, and manufacture of in-vitro molecular diagnostic reagents used in the diagnosis of infectious diseases and human genetic testing.

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