

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000513750-PA-MDSAP-DNK

Initial certification date:
2019-02-15

Expiry Date:
2025-02-14

This is to certify that the management system of

BioLytical Laboratories Inc.

Suite 406, 13251 Delf Place, Richmond, British Columbia V6V 2A2 Canada

F005878

has been found to conform to the Quality Management System standard:

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure
- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 – Production Quality Assurance Procedure

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

This certificate is valid for the following scope:

Design/development, manufacturing, and distribution of near patient in-vitro diagnostic medical devices for Multiplex HIV/Syphilis, HCV and HIV and in-vitro medical devices for self test used as an aid in the diagnosis of HIV status.

Place :
Høvik

Effective Date
2022-03-07



**DNV is an MDSAP authorised
Auditing Organization**



For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Yury Sumtsov
Certificate Authorizer

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

All our Certificates are in blockchain system and as a first step you can validate the certificate details by scanning the QR code on the Certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacture name.