

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
249052-2017-AQ-RGC-NA-PS

Initial certification date:
2 May 2007

Valid:
31 January 2022 – 30 January 2025

This is to certify that the management system of

Goldsite Diagnostics Inc.

No. 103C, 503C, 504D, Technology Building & No. 3A & 4A, Technology Building Annex,
Zhaoshang Sub-district, Nanshan District, Shenzhen, China, 518067
(Unicode:914403007084983777)

and the sites as mentioned in the appendix accompanying this certificate

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

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, Manufacture, Sales and Service of Specific Protein Analyzers, Chemiluminescence Immunoassay Analyzers, Blood Gas Analyzers, Clinical Chemistry Analyzers, Time-resolved Fluoroimmunoassay Analyzers, Glycated Hemoglobin Analyzers and Design, Manufacture and Sales of the Reagents Thereof.

Place and date:
Høvik, 13 September 2021



MSYS 018

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

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management representative

Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Goldsite Diagnostics Inc.	No. 3A & 4A, Technology Building Annex, Zhaoshang Sub-district, Nanshan District, Shenzhen, China, 518067	Manufacture of Specific Protein Analyzers, Chemiluminescence Immunoassay Analyzers, Blood Gas Analyzers, Clinical Chemistry Analyzers, Time-resolved Fluoroimmunoassay Analyzers, Glycated Hemoglobin Analyzers and the Reagents Thereof.
Goldsite Diagnostics Inc.	No. 103C, 503C, 504D, Technology Building, Zhaoshang Sub-district, Nanshan District, Shenzhen, China, 518067	Design, Warehouse and Distribution Management and Sales of Specific Protein Analyzers, Chemiluminescence Immunoassay Analyzers, Blood Gas Analyzers, Clinical Chemistry Analyzers, Time-resolved Fluoroimmunoassay Analyzers, Glycated Hemoglobin Analyzers and the Reagents Thereof and Service of the Above Analyzers.