

10 September 2021

**ISO 13485 certificate**

To Whom It May Concern

I hereby certify that the attached copy of our ISO13485:2016 certificate (Certificate No. FM 717824) is true and accurate.

Certified True and Correct



Penny White  
Senior Manager, Regulatory Affairs  
SEKISUI Diagnostics PEI Inc.



All of which has been sworn and certified true and correct content before Chris Montigny,  
Notary Public, at Charlottetown, Queens County, Prince Edward Island, this 10 day of  
Sept, 2021.





ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI CANADA  
EMBASSY OF THE S.R. OF VIETNAM IN CANADA  
CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION

1. Quốc gia:  
Country Viet Nam
- Giấy tờ, tài liệu này  
This public document
2. do Ông (Bà):  
has been signed by Tina Wishak ký
3. với chức danh: Thừa ủy quyền Thứ trưởng Ngoại giao  
acting in the capacity of
4. và con dấu của: Bộ Ngoại giao, Thương mại và Phát triển Ca-na-đa  
bears the seal/stamp of

Được chứng nhận/hợp pháp hóa lãnh sự  
Certified

5. tại  
at Ót-ta-oa 6. Ngày .....<sup>10</sup> /<sup>12</sup> /2021  
the
7. Cơ quan cấp: Đại sứ quán Việt Nam tại Ca-na-đa  
by
8. Số: 77/12 /2021/CNLS/HPHLS  
Nº

Ký tên và đóng dấu  
Signature and Seal/Stamp  
Tham tán

  
Nguyễn Văn Hiến





By Royal Charter

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Sekisui Diagnostics P.E.I. Inc  
70 Watts Avenue  
Charlottetown  
Prince Edward Island  
C1E 2B9  
Canada

Holds Certificate No:

**FM 717824**

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

Design & development, manufacture and distribution of in-vitro diagnostic test kits and invitro diagnostic reagents used in the diagnosis and management of disease status, drugs of abuse, protein metabolism and blood analytes and for therapeutic drug monitoring.



*Gary E Slack*

For and on behalf of BSI:

\_\_\_\_\_  
Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 1996-08-16

Latest Revision Date: 2021-01-04

Effective Date: 2021-01-04

Expiry Date: 2023-09-24

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...making excellence a habit.™

*TRUE AND CORRECT COPY*

*Cl Mary  
Sept 10/21*

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory) To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.