



Declaration of Conformity

PRODUCT IDENTIFICATION

| Product name | Model/number |
|--|----------------|
| Fecal Occult Blood Test Devices QuickProfile Fecal Occult Blood Test Card QuickProfile Fecal Occult Blood Test Strip | 72001 72006 |

MANUFACTURER

| Name of company | Address | Representative |
|-----------------------------|---|----------------|
| LumiQuick Diagnostics, Inc. | 2946 Scott Blvd. Santa Clara, CA 95054 USA | Jeff Wang |

AUTHORIZED REPRESENTATIVE

| Name of company | Address | Telephone/email |
|-----------------|---|--|
| Emergo Europe | Prinsessegracht 20 2514 AP The Hague, Netherlands | +31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com |

CONFORMITY ASSESSMENT

| Device classification | Route to compliance | Standards applied |
|-----------------------|---|-------------------|
| Class: Self-Certify | Annex III of IVDD 98/79/EC Council Directive | ISO 13485:2003 |

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager

SIGNATURE:

DATE: 28/04/2017