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CERTIFICATE OF VALIDATION

Gen5™

All GEN5 versions including 3.09.07

I hereby certify that all versions of Gen5 software have been fully validated to operate per written product specifications. This validation was conducted utilizing several controlled protocols, which challenged the data transfer, data reduction and instrument interface functionality. The integrity of the Microsoft® Excel spreadsheet data transfer and operation was also validated. Additionally, the Electronic Signature aspects of the software (GEN5SECURE, GEN5SECUREIPRIME, GEN5SECUREIPLUS, GEN5IVD and GEN5IVDIPLUS) were fully validated per US FDA's 21 CFR Part 11 software requirements. All software validation activities are certified to meet the US FDA and ISO 13485 requirements.

The software validation documentation, Master Software Copy, and Source Code are available for review by authorized agents of a customer, US FDA, Health Canada, the European Community or other qualified government bureaus at:

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I hereby certify that the above information is true and accurate:

Kelly A. Lynch 31 January 2020
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