


**BD**

Declaration of Conformity

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|---|---|-----------------|
| Manufacturer | GeneOhm Sciences Canada, Inc. 2555 Boul. du Parc-Technologique Québec, QC G1P 4S5, Canada Tel.: (418) 780-5800 Fax: (418) 780-5849 | |
| Authorized Representative | BENEX Limited Pottery Road, Dun Laoghaire, Co. Dublin, Ireland Tel. : + 353.1.202.5222 Fax : + 353.1.202.5388 | |
| Conformity Assessment Procedure | Annex IV (Full Quality Assurance System) of the IVD Directive 98/79/EC, Notified Body: BSI 2797 Certificate Number: CE 602592 | |
| Product(s): | Product Name | Cat. No. |
| | BD MAX™ CT/GC/TV | 442970 |
| | BD MAX™ CT/GC | 442969 |
| We hereby declare that the above mentioned product(s) comply with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices. This declaration is issued under the sole responsibility of GeneOhm Sciences Canada, Inc. | | |
| Date | June 20, 2019 | |
| Name and Authority | Carole E. Ledford International Regulatory Affairs Sr. Manager BD Diagnostic Systems | |
| Signature |  | |