BD Declaration of Conformity

Manufacturer:	BD Kiestra B.V. Marconilaan 6 9207 JC Drachten The Netherlands
Conformity Assessment Procedure:	Annex III of the IVD Directive 98/79/EC
Products:	BD Kiestra™ TLA containing any of the following: 447167 ProceedA TLA Upgrade Medium 447169 ProceedA TLA Upgrade Large 447206 BD Kiestra™ ReadA™ Compact (covered by its' own Declaration of Conformity (DOC) and not on the TLA DOC) 447208 SorterA TLA 18-3 447209 SorterA TLA 18-6 447210 SorterA TLA 24-3 447211 SorterA TLA 24-6 447212 BarcodA TLA 447213 BD KiestraTM InoqulA+™ TLA 447214 BD Kiestra™ InoqulA+™ Slide Preparation Module (covered by its' own DOC and not on the TLA DOC) 447272 BD Kiestra™ InoqulA™ Magnetic Beads (covered by its' own DOC and not on the TLA DOC) 447900 ProceedA TLA 4 447901 ProceedA TLA 8 447904 ProceedA TLA 10 447902 ProceedA TLA 12 447903 ProceedA TLA Upgrade Small

We hereby declare that the above mentioned products comply with the European In Vitro Diagnostic Directive 98/79/EC and its relevant transposition into national laws of the member states into which we place the devices.

Signed in Drachten:	12 December 2019
Name and Authority:	Karin Brands Manager Regulatory Affairs
Signature: