EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	BD Kiestra, B.V. Marconilaan 6 9207 JC Drachten The Netherlands		
Manufacturer SRN:	NL-MF-000018863		
Authorised Representative:	Not Applicable		
Authorised Representative SRN:	Not Applicable		
Product:	**Catalog Number**	**Product Trade Name**	
	446231	BD Kiestra™ Slides	
	446958	BD Kiestra™ BarcodA Track	
	446971	BD Kiestra™ Slide Processing Module	
	446972	BD Kiestra™ InoqulA Track	
	446973	BD Kiestra™ InoqulA	
	447202	BD Kiestra™ InoqulA+™	
	447208	BD Kiestra™ SorterA TLA 18-3	
	447209	BD Kiestra™ SorterA TLA 18-6	
	447210	BD Kiestra™ SorterA TLA 24-3	
	447211	BD Kiestra™ SorterA TLA 24-6	
	447212	BD Kiestra™ BarcodA TLA	
	447213	BD Kiestra™ InoqulA+™ TLA	
	447214	BD Kiestra™ InoqulA+™ Slide Preparation Module	
	447272	BD Kiestra™ InoqulA™ Magnetic Beads	
Basic UDI-DI:	**Catalog Number**	**Product Trade Name**	**Basic UDI-DI**
	446231	BD Kiestra™ Slides	038290LSUVLPKFPV
	446958	BD Kiestra™ BarcodA Track	
	446971	BD Kiestra™ Slide Processing Module	
	446972	BD Kiestra™ InoqulA Track	
	446973	BD Kiestra™ InoqulA	

	447202	BD Kiestra™ InoqulA+™	
	447214	BD Kiestra™ InoqulA+™ Slide Preparation Module	
	447272	BD Kiestra™ InoqulA™ Magnetic Beads	
	447208	BD Kiestra™ SorterA TLA 18-3	038290IAVSLVOZEG
	447209	BD Kiestra™ SorterA TLA 18-6	
	447210	BD Kiestra™ SorterA TLA 24-3	
	447211	BD Kiestra™ SorterA TLA 24-6	
	447212	BD Kiestra™ BarcodA TLA	
	447213	BD Kiestra™ InoqulA+™ TLA	
Risk Class and Rule:	Class A, Rule 5 (b) and Rule 5 (a)		
Intended Purpose:	**Catalog Number**	**Product Trade Name**	**Intended Purpose**
	446231	BD Kiestra™ Slides	The BD Kiestra™ InoqulA and BD Kiestra™ InoqulA+™ is an *in vitro* diagnostic device system which is intended to automate specimen processing according to user-defined procedures and protocols. In Fully Automated (FA) mode, this includes opening and closing sample container(s), barcoding, inoculating and streaking plated media, and inoculating tubes and slides. In Semi-Automated (SA) mode, dishes are automatically selected, barcoded, streaked in a pre-configured pattern while
	446958	BD Kiestra™ BarcodA Track	
	446971	BD Kiestra™ Slide Processing Module	
	446972	BD Kiestra™ InoqulA Track	
	446973	BD Kiestra™ InoqulA	
	447202	BD Kiestra™ InoqulA+™	
	447208	BD Kiestra™ SorterA TLA 18-3	
	447209	BD Kiestra™ SorterA TLA 18-6	
	447210	BD Kiestra™ SorterA TLA 24-3	
	447211	BD Kiestra™ SorterA TLA 24-6	

	447212	BD Kiestra™ BarcodA TLA	the user manually inoculates dishes, tubes and slides. An optional biosafety cabinet on the SA module provides personnel, product, and environmental protection. The BD Kiestra™ InoqulA and BD Kiestra™ InoqulA+™ is indicated for use in the clinical laboratory.
	447213	BD Kiestra™ InoqulA+™ TLA	
	447214	BD Kiestra™ InoqulA+™ Slide Preparation Module	
	447272	BD Kiestra™ InoqulA™ Magnetic Beads	
Notified Body:	Not applicable, devices self-certified		

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s):

- Regulation (EU) 2017/746 on *In vitro* Diagnostic Medical Devices.
- Directive 2011/65/EU on Restriction of the use of certain hazardous substances in electrical and electronic equipment as amended by Commission Delegated Directive 2015/863 (RoHS)

Conformity Assessment Route:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☒ ANNEX I & II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common Specification have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
446231	BD Kiestra™ Slides[a]	Class A
446958	BD Kiestra™ BarcodA Track	Class A
446971	BD Kiestra™ Slide Processing Module	Class A

446972	BD Kiestra™ InoqulA Track	Class A
446973	BD Kiestra™ InoqulA	Class A
447202	BD Kiestra™ InoqulA+™	Class A
447208	BD Kiestra™ SorterA TLA 18-3[a]	Class A
447209	BD Kiestra™ SorterA TLA 18-6[a]	Class A
447210	BD Kiestra™ SorterA TLA 24-3[a]	Class A
447211	BD Kiestra™ SorterA TLA 24-6[a]	Class A
447212	BD Kiestra™ BarcodA TLA[a]	Class A
447213	BD Kiestra™ InoqulA+™ TLA[a]	Class A
447214	BD Kiestra™ InoqulA+™ Slide Preparation Module[a]	Class A
447272	BD Kiestra™ InoqulA™ Magnetic Beads[a]	Class A

[a] Product is not in scope for RoHS Directive 2011/65/EU

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	BD Kiestra B.V.
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	DocuSigned by: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 | 11:26:37 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Addition of 446231 and 446971
03	Addition of 446972 and 446958

Version:	Detailed Change Description:
04	Revision 04 Template change. Updated Authorised representative and Authorised representative SRN. Changed SKU to Product catalog in Product, Basic – UDI and Intended Purpose. Updated Conformity Assessment Route, Common specifications table left as blank, Corrected on behalf of in authorized signatory and formatting changes.