



EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152, USA		
Manufacturer SRN:	US-MF-000018910		
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26, Ireland		
Authorised Representative SRN:	IE-AR-000007610		
Product:	Catalog Number	Product Trade Name	
	444063	BD Kiestra™ IdentifA	
	444061	BD Kiestra™ IdentifA TLA Connection	
	444062	BD Kiestra™ IdentifA WCA Connection	
	444064	BD Kiestra™ ID AST Calibrator Kit	
	246100	BD Kiestra™ Isolate Suspension Cuvette Array	
	444060	BD Kiestra™ IdentifA Manual Infeed	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	444063	BD Kiestra™ IdentifA	038290IZCYQAPNK9
	444061	BD Kiestra™ IdentifA TLA Connection	
	444062	BD Kiestra™ IdentifA WCA Connection	
	444064	BD Kiestra™ ID AST Calibrator Kit	
	246100	BD Kiestra™ Isolate Suspension Cuvette Array	
	444060	BD Kiestra™ IdentifA Manual Infeed	
Risk Class and Rule:	Class A, Rule 5 (b)		

Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	444063	BD Kiestra™ IdentifA	The BD Kiestra™ IdentifA module is an automated <i>in vitro</i> diagnostic specimen preparation system for use with the BD Kiestra™ Laboratory Automation Solution to prepare MALDI targets for the Bruker MALDI Biotyper® CA System for the qualitative identification and differentiation of microorganisms using matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) analysis of colonies grown on plated culture media from human specimens. The BD Kiestra™ IdentifA is indicated for use in the clinical laboratory with the BD Kiestra™ ReadA™ Compact and Bruker MALDI Biotyper® CA System to aid in the diagnosis of bacterial and fungal infections.
	444061	BD Kiestra™ IdentifA TLA Connection	
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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 <i>In vitro</i> 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 these product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
444063	BD Kiestra™ IdentifA	Class A
444061	BD Kiestra™ IdentifA TLA Connection	Class A
444062	BD Kiestra™ IdentifA WCA Connection	Class A
444064	BD Kiestra™ ID AST Calibrator Kit ^a	Class A
246100	BD Kiestra™ Isolate Suspension Cuvette Array ^a	Class A
444060	BD Kiestra™ IdentifA Manual Infeed	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:	Becton, Dickinson and Company
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	DocuSigned by: <i>Anne Zavertnik</i>  Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:26:21 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template change. Updated Conformity Assessment Route, Common specifications table left as blank and formatting changes.