

## 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	
	446948	BD Kiestra™ ReadA	
	447206	BD Kiestra™ ReadA™ Compact	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	446948	BD Kiestra™ ReadA	038290NJLELBHF8B
	447206	BD Kiestra™ ReadA™ Compact	
Risk Class and Rule:	Class A, Rule 5(b)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	446948	BD Kiestra™ ReadA	The BD Kiestra™ ReadA and BD Kiestra™ ReadA™ Compact is an <i>in vitro</i> diagnostic device system which consists of an incubator and a camera module. The BD Kiestra™ ReadA and BD Kiestra™ ReadA™ Compact is used to incubate plates and to create images of plates. Plates are automatically removed from the incubator, photographed, and returned to the incubator or transported to another specified destination.
	447206	BD Kiestra™ ReadA™ Compact	

			The BD Kiestra™ ReadA and BD Kiestra™ ReadA™ Compact is indicated for use in the clinical laboratory.
<b>Notified Body:</b>	Not applicable, devices self-certified		
<p>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):</p> <ul style="list-style-type: none"><li>• Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices.</li><li>• 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)</li></ul>			

### Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input checked="" type="checkbox"/> ANNEX I & II+III	N/A

### Common Specifications (CS):


Number:	Title:	Full or Partial Application:

Common Specification have not been issued for these products.

### Devices Covered by this DoC:

SKU#	Device Name	Device Class
446948	BD Kiestra™ ReadA	Class A
447206	BD Kiestra™ ReadA™ Compact <sup>a</sup>	Class A

<sup>a</sup> 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:	<p>DocuSigned by:</p> <p><i>Anne Zavertnik</i></p> <p> Signer Name: Anne Zavertnik  Signing Reason: I approve this document  Signing Time: 10-Nov-2022   11:26:29 PM GMT  DC6A638A32E64A8A91F9D8DE330F0415</p>

## 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.