EU DECLARATION OF CONFORMITY (DoC)

<table>
<tr><td>Manufacturer:</td><td>Becton Dickinson GmbH
Tullastrasse 8 – 12
69126 Heidelberg, Germany</td></tr>
<tr><td>Manufacturer SRN:</td><td>DE-MF-000018170</td></tr>
<tr><td>Authorised Representative:</td><td>Not applicable</td></tr>
<tr><td>Authorised Representative SRN:</td><td>Not applicable</td></tr>
<tr><td>Product:</td><td>
<table>
<tr><th>Catalog Number</th><th>Product Trade Name</th></tr>
<tr><td>257480</td><td rowspan="2">BD BBL™ CHROMagar™ Candida</td></tr>
<tr><td>254106</td></tr>
<tr><td>257481</td><td rowspan="2">BD BBL™ CHROMagar™ Orientation</td></tr>
<tr><td>254107</td></tr>
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<tr><td>Basic UDI-DI:</td><td>
<table>
<tr><th>Catalog Number</th><th>Product Trade Name</th><th>Basic UDI-DI</th></tr>
<tr><td>257480</td><td rowspan="2">BD BBL™ CHROMagar™ Candida</td><td rowspan="2">038290AYRSDQMGGX</td></tr>
<tr><td>254106</td></tr>
<tr><td>257481</td><td rowspan="2">BD BBL™ CHROMagar™ Orientation</td><td rowspan="2">038290HGKEQCQC4N</td></tr>
<tr><td>254107</td></tr>
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<tr><td>Risk Class and Rule:</td><td>Class B, Rule 6</td></tr>
<tr><td>Notified Body:</td><td>BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9,
1066 EP Amsterdam, The Netherlands
Notified Body Number: 2797</td></tr>
<tr><td>Intended Purpose:</td><td>
<table>
<tr><th>Catalog Number</th><th>Product Trade Name</th><th>Intended Purpose</th></tr>
<tr><td>257480</td><td>BD BBL™ CHROMagar™ Candida</td><td>BD BBL™ CHROMagar™ Candida is a qualitative medium for isolation and direct detection of Candida albicans, C. tropicalis, and C. krusei. The medium is used as an aid in diagnosis on fecal, respiratory, and vaginal specimens from patients in a healthcare setting where testing for these organisms is medically indicated. It is</td></tr>
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	254106		inhibitory to bacteria and can also be used as a selective isolation medium for other yeast species and for filamentous fungi.
	257481	BD BBL™ CHROMagar™ Orientation	BD BBL™ CHROMagar™ Orientation is a nonselective medium for the isolation, direct identification, differentiation and enumeration of urinary tract pathogens. BD BBL™ CHROMagar™ Orientation allows for the quantitative differentiation and direct detection of *Escherichia coli* and *Enterococcus* without confirmatory testing. Furthermore, the medium allows the identification of most *S. saprophyticus* and *S. agalactiae* strains, the *Klebsiella-Enterobacter-Serratia* (=KES) and *Proteus-Morganella-Providencia* (=PMP) groups. The medium is used as an aid in diagnosis on urine specimens from patients suspected of having a urinary tract infection.
	254107		

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.
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Conformity Assessment Route:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A
☒ ANNEX IX Full Quality System	EC CERTIFICATE No.: 805735
☐ ANNEX X Type Examination	EC CERTIFICATE No.: N/A
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A
☐ ANNEX II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common Specifications have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
257480	BD BBL™ CHROMagar™ Candida	Class B
254106		Class B
257481	BD BBL™ CHROMagar™ Orientation	Class B
254107		Class B

Authorised Signatory:	
Name & Title:	Jeffrey Zinza, Vice President, Regulatory Affairs
On behalf of:	Becton Dickinson GmbH
Place of Issue:	Sparks, MD, USA
Date of Issue:	05-May-2025
Signature:	Signed by: Jeffrey Zinza Signer Name: Jeffrey Zinza Signing Reason: I approve this document Signing Time: 02-May-2025 | 7:57:30 AM PDT 229102DCD5EB4A29AEE688DE6534A8CA

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release