



Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	230705 - BD BBL Sensi-Disc Ampicillin - 10 µg (see Annex A for list of variants) -
We hereby declare that the above mentioned product(s) manufactured after 3/30/2020 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices. This declaration is issued under the sole responsibility of Becton, Dickinson and Company.	
Signed In Baltimore:	3/30/2020
Name and Authority:	Bradford M. Spring , VP, Regulatory Affairs
Signature:	

Technical File Number: BALTER230705

Annex A

Multiple Antibacterial Sensi Disc – GMDN 45352

BALTER230705 version D revision N/A

Primary Catalog Number and Product Name:

230705	BD BBL™ Sensi-Disc™ Ampicillin - 10 µg
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Variants:

215358	BD BBL™ Sensi-Disc™ Ceftazidime/Avibactam 10/4 µg
230725	BD BBL™ Sensi-Disc™ Cephalothin - 30 µg
230729	BD BBL™ Sensi-Disc™ Chloramphenicol - 5 µg
230733	BD BBL™ Sensi-Disc™ Chloramphenicol - 30 µg
230749	BD BBL™ Sensi-Disc™ Colistin - 10 µg
230793	BD BBL™ Sensi-Disc™ Erythromycin - 15 µg
230809	BD BBL™ Sensi-Disc™ Furazolidone - 100 µg
230874	BD BBL™ Sensi-Disc™ Nalidixic Acid - 30 µg
230886	BD BBL™ Sensi-Disc™ Novobiocin - 5 µg
230906	BD BBL™ Sensi-Disc™ Oxacillin - 1 µg
230918	BD BBL™ Sensi-Disc™ Penicillin - 10 units
230942	BD BBL™ Sensi-Disc™ Streptomycin - 10 µg
230998	BD BBL™ Sensi-Disc™ Tetracycline - 30 µg
231030	BD BBL™ Sensi-Disc™ Vancomycin - 5 µg
231034	BD BBL™ Sensi-Disc™ Vancomycin - 30 µg
231149	BD BBL™ Sensi-Disc™ Nitrofurantoin - 300 µg
231213	BD BBL™ Sensi-Disc™ Clindamycin - 2 µg
231227	BD BBL™ Sensi-Disc™ Gentamicin - 10 µg
231250	BD BBL™ Sensi-Disc™ Minocycline - 30 µg
231251	BD BBL™ Sensi-Disc™ Minocycline - 30 µg
231263	BD BBL™ Sensi-Disc™ Ampicillin - 2 µg
231264	BD BBL™ Sensi-Disc™ Ampicillin - 10 µg
231267	BD BBL™ Sensi-Disc™ Bacitracin - 2 units
231268	BD BBL™ Sensi-Disc™ Bacitracin - 10 units
231271	BD BBL™ Sensi-Disc™ Cephalothin - 30 µg
231274	BD BBL™ Sensi-Disc™ Chloramphenicol - 30 µg

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231275	BD BBL™ Sensi-Disc™ Clindamycin - 2 µg
231276	BD BBL™ Sensi-Disc™ Cloxacillin - 1 µg
231278	BD BBL™ Sensi-Disc™ Colistin - 10 µg
231286	BD BBL™ Sensi-Disc™ Doxycycline - 30 µg
231289	BD BBL™ Sensi-Disc™ Erythromycin - 2 µg
231290	BD BBL™ Sensi-Disc™ Erythromycin - 15 µg
231292	BD BBL™ Sensi-Disc™ Nitrofurantoin - 100 µg
231293	BD BBL™ Sensi-Disc™ Nitrofurantoin - 300 µg
231296	BD BBL™ Sensi-Disc™ Sulfisoxazole - 0.25 mg
231297	BD BBL™ Sensi-Disc™ Sulfisoxazole - 1.0 mg
231299	BD BBL™ Sensi-Disc™ Gentamicin - 10 µg
231301	BD BBL™ Sensi-Disc™ Kanamycin - 30 µg
231302	BD BBL™ Sensi-Disc™ Lincomycin - 2 µg
231309	BD BBL™ Sensi-Disc™ Nafcillin - 1 µg
231311	BD BBL™ Sensi-Disc™ Nalidixic Acid - 30 µg
231312	BD BBL™ Sensi-Disc™ Neomycin - 5 µg
231313	BD BBL™ Sensi-Disc™ Neomycin - 30 µg
231314	BD BBL™ Sensi-Disc™ Novobiocin - 5 µg
231315	BD BBL™ Sensi-Disc™ Novobiocin - 30 µg
231319	BD BBL™ Sensi-Disc™ Oxacillin - 1 µg
231320	BD BBL™ Sensi-Disc™ Penicillin - 2 units
231321	BD BBL™ Sensi-Disc™ Penicillin - 10 units
231324	BD BBL™ Sensi-Disc™ Polymyxin B - 300 units
231326	BD BBL™ Sensi-Disc™ Sulfachloropyridazine - 1.0 mg
231328	BD BBL™ Sensi-Disc™ Streptomycin - 10 µg
231331	BD BBL™ Sensi-Disc™ Sulfadiazine - 0.25 mg
231337	BD BBL™ Sensi-Disc™ Sulfathiazole - 0.25 mg
231342	BD BBL™ Sensi-Disc™ Oxytetracycline - 30 µg
231343	BD BBL™ Sensi-Disc™ Tetracycline - 5 µg
231344	BD BBL™ Sensi-Disc™ Tetracycline - 30 µg
231345	BD BBL™ Sensi-Disc™ Sulfamethizole - 0.25 mg

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231349	BD BBL™ Sensi-Disc™ Triple Sulfa - 0.25 mg
231350	BD BBL™ Sensi-Disc™ Triple Sulfa - 1.0 mg
231352	BD BBL™ Sensi-Disc™ Vancomycin - 5 µg
231353	BD BBL™ Sensi-Disc™ Vancomycin - 30 µg
231536	BD BBL™ Sensi-Disc™ Sulfamethoxazole/Trimethoprim - 23.75/1.25 µg
231539	BD BBL™ Sensi-Disc™ Sulfamethoxazole/Trimethoprim - 23.75/1.25 µg
231541	BD BBL™ Sensi-Disc™ Rifampin - 5 µg
231544	BD BBL™ Sensi-Disc™ Rifampin - 5 µg
231555	BD BBL™ Sensi-Disc™ Carbenicillin - 100 µg
231568	BD BBL™ Sensi-Disc™ Tobramycin - 10 µg
231569	BD BBL™ Sensi-Disc™ Tobramycin - 10 µg
231590	BD BBL™ Sensi-Disc™ Cefoxitin - 30 µg
231591	BD BBL™ Sensi-Disc™ Cefoxitin - 30 µg
231593	BD BBL™ Sensi-Disc™ Cefazolin - 30 µg
231597	BD BBL™ Sensi-Disc™ Amikacin - 30 µg
231599	BD BBL™ Sensi-Disc™ Cinoxacin - 100 µg
231601	BD BBL™ Sensi-Disc™ Trimethoprim - 5 µg
231603	BD BBL™ Sensi-Disc™ Netilmicin - 30 µg
231605	BD BBL™ Sensi-Disc™ Metronidazole - 80 µg
231606	BD BBL™ Sensi-Disc™ Cefotaxime - 30 µg
231607	BD BBL™ Sensi-Disc™ Cefotaxime - 30 µg
231608	BD BBL™ Sensi-Disc™ Piperacillin - 100 µg
231609	BD BBL™ Sensi-Disc™ Piperacillin - 100 µg
231611	BD BBL™ Sensi-Disc™ Moxalactam - 30 µg
231613	BD BBL™ Sensi-Disc™ Cefoperazone - 75 µg
231615	BD BBL™ Sensi-Disc™ Mezlocillin - 75 µg
231619	BD BBL™ Sensi-Disc™ Ticarcillin - 75 µg
231621	BD BBL™ Sensi-Disc™ Cefuroxime - 30 µg
231623	BD BBL™ Sensi-Disc™ Ceftizoxime - 30 µg
231625	BD BBL™ Sensi-Disc™ Azlocillin - 75 µg
231628	BD BBL™ Sensi-Disc™ Amoxicillin/Clavulanic Acid - 20/10 µg

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231629	BD BBL™ Sensi-Disc™ Amoxicillin/Clavulanic Acid - 20/10 µg
231632	BD BBL™ Sensi-Disc™ Ceftazidime - 30 µg
231633	BD BBL™ Sensi-Disc™ Ceftazidime - 30 µg
231634	BD BBL™ Sensi-Disc™ Ceftriaxone - 30 µg
231635	BD BBL™ Sensi-Disc™ Ceftriaxone - 30 µg
231637	BD BBL™ Sensi-Disc™ Spectinomycin - 100 µg
231640	BD BBL™ Sensi-Disc™ Aztreonam - 30 µg
231641	BD BBL™ Sensi-Disc™ Aztreonam - 30 µg
231643	BD BBL™ Sensi-Disc™ Cefonicid - 30 µg
231644	BD BBL™ Sensi-Disc™ Imipenem - 10 µg
231645	BD BBL™ Sensi-Disc™ Imipenem - 10 µg
231647	BD BBL™ Sensi-Disc™ Norfloxacin - 10 µg
231648	BD BBL™ Sensi-Disc™ Ticarcillin/Clavulanic Acid - 75/10 µg
231649	BD BBL™ Sensi-Disc™ Ticarcillin/Clavulanic Acid - 75/10 µg
231653	BD BBL™ Sensi-Disc™ Cefaclor - 30 µg
231656	BD BBL™ Sensi-Disc™ Cefotetan - 30 µg
231657	BD BBL™ Sensi-Disc™ Ciprofloxacin - 5 µg
231658	BD BBL™ Sensi-Disc™ Ciprofloxacin - 5 µg
231660	BD BBL™ Sensi-Disc™ Ampicillin/Sulbactam - 10/10 µg
231662	BD BBL™ Sensi-Disc™ Enoxacin - 10 µg
231664	BD BBL™ Sensi-Disc™ Cefixime - 5 µg
231666	BD BBL™ Sensi-Disc™ Cefmetazole - 30 µg
231672	BD BBL™ Sensi-Disc™ Ofloxacin - 5 µg
231673	BD BBL™ Sensi-Disc™ Cefpodoxime - 10 µg
231674	BD BBL™ Sensi-Disc™ Cefpodoxime - 10 µg
231678	BD BBL™ Sensi-Disc™ Clarithromycin - 15 µg
231682	BD BBL™ Sensi-Disc™ Azithromycin - 15 µg
231684	BD BBL™ Sensi-Disc™ Cefprozil - 30 µg
231686	BD BBL™ Sensi-Disc™ Lomefloxacin - 10 µg
231691	BD BBL™ Sensi-Disc™ Piperacillin/Tazobactam - 100/10 µg
231692	BD BBL™ Sensi-Disc™ Piperacillin/Tazobactam - 100/10 µg

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231693	BD BBL™ Sensi-Disc™ Gentamicin - 120 µg
231694	BD BBL™ Sensi-Disc™ Streptomycin - 300 µg
231696	BD BBL™ Sensi-Disc™ Cefepime - 30 µg
231703	BD BBL™ Sensi-Disc™ Meropenem - 10 µg
231704	BD BBL™ Sensi-Disc™ Meropenem - 10 µg
231705	BD BBL™ Sensi-Disc™ Levofloxacin - 5 µg
231706	BD BBL™ Sensi-Disc™ Levofloxacin - 5 µg
231707	BD BBL™ Sensi-Disc™ Sparfloxacin - 5 µg
231709	BD BBL™ Sensi-Disc™ Fosfomycin -200 µg
231713	BD BBL™ Sensi-Disc™ Cefdinir - 5 µg
231721	BD BBL™ Sensi-Disc™ Quinupristin/Dalfopristin (Synercid) - 15 µg
231751	BD BBL™ Sensi-Disc™ Cefotaxime/Clavulanic Acid - 30/10 µg
231752	BD BBL™ Sensi-Disc™ Cefotaxime/Clavulanic Acid - 30/10 µg
231753	BD BBL™ Sensi-Disc™ Ceftazidime/Clavulanic Acid - 30/10 µg
231754	BD BBL™ Sensi-Disc™ Ceftazidime/Clavulanic Acid - 30/10 µg
231755	BD BBL™ Sensi-Disc™ Fosfomycin - 200 µg
231758	BD BBL™ Sensi-Disc™ Moxifloxacin - 5 µg
231760	BD BBL™ Sensi-Disc™ Gatifloxacin - 5 µg
231761	BD BBL™ Sensi-Disc™ Linezolid - 30 µg
231762	BD BBL™ Sensi-Disc™ Linezolid - 30 µg
232087	BD BBL™ Sensi-Disc™ Tigecycline - 15 µg
232174	BD BBL™ Sensi-Disc™ Ertapenem - 10 µg
232175	BD BBL™ Sensi-Disc™ Ertapenem - 10 µg
232208	BD BBL™ Sensi-Disc™ Tigecycline - 15µg
232218	BD BBL™ Sensi-Disc™ Ceftazidime/Avibactam - 30/20 µg
232219	BD BBL™ Sensi-Disc™ Doripenem - 10 µg
232228	BD BBL™ Sensi-Disc™ Gentamicin - 30 µg
232231	BD BBL™ Sensi-Disc™ Ceftaroline - 30 µg
232235	BD BBL™ Sensi-Disc™ Piperacillin & Tazobactam – 30/6 µg
232236	BD BBL™ Sensi-Disc™ Gentamicin - 30 µg
232237	BD BBL™ Sensi-Disc™ Ceftazidime - 10 µg

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232244	BD BBL™ Sensi-Disc™ Ceftaroline - 5 µg
266647	BD BBL™ Sensi-Disc™ Telithromycin - 15µg
291269	BD BBL™ Sensi-Disc™ Ampicillin - 25 µg

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