



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) - v
We hereby declare that the above mentioned product(s) manufactured after 2/10/2015 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.	
Signed In Baltimore:	2/10/2015
Name and Authority:	Bradford M. Spring, VP, Regulatory Affairs
Signature:	

Technical File Number: BALTER230705

Print

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

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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
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

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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

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231344	BD BBL™ Sensi-Disc™ Tetracycline - 30 µg
231345	BD BBL™ Sensi-Disc™ Sulfamethizole - 0.25 mg
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 with Trimethoprim - 23.75/1.25 µg
231539	BD BBL™ Sensi-Disc™ Sulfamethoxazole with 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

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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 with Clavulanic Acid - 20/10 µg
231629	BD BBL™ Sensi-Disc™ Amoxicillin with 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

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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 with Clavulanic Acid - 75/10 µg
231649	BD BBL™ Sensi-Disc™ Ticarcillin with 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 with 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

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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
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

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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
232211	BD BBL™ Sensi-Disc™ TRIS-EDTA
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

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232237	BD BBL™ Sensi-Disc™ Ceftazidime - 10 µg
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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