



Medicines & Healthcare products  
Regulatory Agency

151 Buckingham Palace Road  
London SW1W 9SZ  
United Kingdom

mhra.gov.uk

**SAE 188/V6185/1**

**25/07/2016 11:35:21**

## **Medicines and Healthcare Products Regulatory Agency**

On behalf of the Department of Health

**CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS  
TO**

**KOREA (REPUBLIC OF)**

It is hereby certified that, on the basis of information provided, the products named below and detailed in the attached schedule (if applicable), which are manufactured by; **Becton, Dickinson and Company USA**, have been affixed with the CE mark under the In-Vitro Diagnostic Medical Devices Directive 98/79/EC and / or the Medical Devices Directive 93/42/EEC (as amended) which was transposed into UK legislation (UK Medical Devices Regulations 2002 S.I. No. 618, as amended), and therefore may be freely sold in all member states of the European Economic Area including the United Kingdom.

### **See attached schedule**

Where appropriate, Certificates of Free Sale are issued as a service to UK exporters. A Certificate of Free Sale should not be taken as a Government endorsement of any product that is referred to on the certificate.

Yours sincerely,

**Deanna Brownlie**

Certificate of Free Sale Administration Team  
Signed on Behalf of MHRA



Schedule of Devices requested for	ord-20160725-113428-dpys
Ordered on	25/07/2016
Directive/Class	98/79/EC
Mfr Name	Becton, Dickinson and Company USA

Device Make	Device Model
BD Vacutainer® Luer-Lok™ Access Device Holder with Pre-Attached Multiple Sample Adapter	364902
BD Vacutainer® Blood Transfer Device Holder with Pre-Attached Multiple Sample Female Luer Adapter	364810
BD Microtainer® K2E Tubes	365975
BD Microtainer® Z Tubes	365964
BD Microtainer® LH Tubes	365966
BD Microtainer® SST™ Tubes	365968
BD Microtainer® SST™ Amber Tubes	365979
BD Microtainer® PST™ LH Tubes	365986
BD Microtainer® PST™ LH Amber Tubes	365988
BD Microtainer® FE Microcollection Tubes	365993
BD Microtainer® Quikheel™ Premie Lancet	368102
BD Microtainer® Quikheel™ Lancet	368103
BD Microtainer® Tube Extender	368933

The above products are manufactured by; **BD Caribe Ltd.**, Road 31 Km.24.3, Juncos, PR 00777-4010, Puerto Rico, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Vacutainer® Z (No Additive) Plus Urine Tube	364938
BD Vacutainer® Urine Transfer Straw	364940
BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate Plus Urine Tube	364944
BD Vacutainer® Boric Acid Sodium Borate/Formate Plus C&S Urine Tube	364955
BD Vacutainer® Boric Acid Sodium Borate/Formate Plus C&S Urine Tube	364958
BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate Plus Urine Tube	364959
BD Vacutainer® Boric Acid, Sodium Formate For Urine Only 6ml 13x100m m	364969
BD Vacutainer® Urine Analysis Preservative Tube	364992



BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical	365000
BD Vacutainer® Urinalysis Preservative Plus Urine Tube	365017
BD Microtainer® MAP Microtube for Automated Process K2 EDTA 1.0 mg	363706
BD Microtainer® MAP Microtube for Automated Process K2 EDTA 1.0 mg	363806
BD Vacutainer® Plus Blood Collection Tubes	364305
BD Vacutainer® 9NC 0.109M 0.2 ml Plus Blood Collection Tubes	368273
BD Vacutainer® Blood Collection Tubes 0.129M 9NC	368932
BD Vacutainer® FX 5mg 4mg Plus Blood Collection Tubes	368920
BD Vacutainer® FX 10mg 8mg Plus Blood Collection Tubes	368921
BD Vacutainer® FX 5mg 4mg Plus Tubes	367934
BD Vacutainer® FX 10mg:8mg Plus Blood Collection Tubes	367935
BD Vacutainer® Sodium HeparinN (NH) 33 USP = 33 IU Blood Collection Tubes	367671
BD Vacutainer® K2 EDTA (K2E) Plus Blood Collection Tubes	367862
BD Vacutainer® CPT™ NH: ~130 IU FICOLL™: 2.0mL	362780
BD Vacutainer® CPT™ NC: 0.45 ml FICOLL™: 1.0mL	362781
BD Vacutainer® CPT™ NC: 1.0mL FICOLL™: 2.0mL	362782
BD Vacutainer® PPT™ Plasma Preparation Tube K2E (EDTA) 9.0 mg	362791
BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362794
BD Vacutainer® PPT™ Plasma Preparation Tube K2E 9.0 mg	362795
BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362799
BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362800
BD Vacutainer® Thrombin Tubes	368922
BD Vacutainer® Thrombin Tubes	368923
BD Vacutainer® Thrombin Tubes	368925



BD Vacutainer® Trace Element Serum Plus Blood Collection Tubes	368380
BD Vacutainer® Trace Element K2 EDTA (K2E) Plus Blood Collection Tubes 10.8 mg	368381
BD Vacutainer® Trace Element Serum Plus Blood Collection Tubes	369627
BD Vacutainer® Trace Element K2 EDTA (K2E) Plus Blood Collection Tubes 10.8 mg	369628

The above products are manufactured by; **Becton, Dickinson and Company (BD)**, 150 South First Avenue, Broken Bow, NE 68822, USA, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Vacutainer® Multiple Sample Luer Adapter	367300
BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368652
BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368653
BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368654
BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368655
BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367353
BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367354
BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367355
BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367356
BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	368657
BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	368658
BD Vacutainer® Eclipse™ Blood Collection Needle	368609
BD Vacutainer® Eclipse™ Blood Collection Needle	368610
BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder	368650



BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder	368651
BD Vacutainer® SST™ Blood Collection Tubes	367782
BD Vacutainer® SST™ Plus Blood Collection Tubes	368825
BD Vacutainer® SST™ Plus Blood Collection Tubes	367985
BD Vacutainer® Serum / CAT Plus Blood Collection Tubes	367819
BD Vacutainer® Standard Yellow Holder	364879

The above products are manufactured by; **Becton, Dickinson and Company (BD)**, 1575 Airport Road, Sumter, SC 29153, USA, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Vacutainer® Urine Collection Cups	364941
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The above products are manufactured by; **Becton, Dickinson and Company (BD)**, 150 South First Avenue, Broken Bow, NE 68822, USA; **Becton, Dickinson and Company**, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365030
BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365031
BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365032
BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365033
BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365034
BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365035
BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365036
BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365039
BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365040



BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365042
BD Vacutainer® 9NC 0.109M 0.2 ml Plus Blood Collection Tubes	368273
BD Vacutainer® Plus Blood Collection Tubes	364305

The above products are manufactured by; **Becton, Dickinson and Company**, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Vacutainer® Blood Collection Set	368382
BD Vacutainer® Blood Collection Set	368383
BD Vacutainer® Pronto™ Quick Release Needle Holder	368872

The above products are manufactured by; **NIPRO MEDICAL INDUSTRIES LTD.**, Tatebayashi Plant, 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518, Japan, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Vacutainer® Safety-Lok™ Blood Collection Set	360293
BD Vacutainer® Safety-Lok™ Blood Collection Set	360294
BD Vacutainer® Safety-Lok™ Blood Collection Set	360295
BD Vacutainer® Safety-Lok™ Blood Collection Set	367246
BD Vacutainer® Safety-Lok™ Blood Collection Set	367247
BD Vacutainer® Safety-Lok™ Blood Collection Set	367288
BD Vacutainer® Safety-Lok™ Blood Collection Set	367295
BD Vacutainer® Safety-Lok™ Blood Collection Set	368382
BD Vacutainer® Safety-Lok™ Blood Collection Set	368383



The above products are manufactured by; **NIPRO MEDICAL INDUSTRIES LTD.**, Tatebayashi Plant, 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518, Japan; **Nipro (Thailand) Corporation Limited**, 10/2 Moo 8 Bangnomko, Sena, Phra Nakhon Si Ayutthaya 13110, Thailand, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Vacutainer® Safety-Lok™ Blood Collection Set	367282
BD Vacutainer® Safety-Lok™ Blood Collection Set	367284
BD Vacutainer® Safety-Lok™ Blood Collection Set	367286

The above products are manufactured by; **NIPRO MEDICAL INDUSTRIES LTD.**, Tatebayashi Plant, 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518, Japan; **Nipro (Thailand) Corporation Limited**, 10/2 Moo 8 Bangnomko, Sena, Phra Nakhon Si Ayutthaya 13110, Thailand; **Becton, Dickinson and Company (BD)**, 1575 Airport Road, Sumter, SC 29153, USA, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Vacutainer® Push Button Blood Collection Set	367323
BD Vacutainer® Push Button Blood Collection Set	367324
BD Vacutainer® Push Button Blood Collection Set	367326
BD Vacutainer® Push Button Blood Collection Set	367341
BD Vacutainer® Push Button Blood Collection Set	367342
BD Vacutainer® Push Button Blood Collection Set	367344
BD Vacutainer® Push Button Blood Collection Set	367335
BD Vacutainer® Push Button Blood Collection Set	367336
BD Vacutainer® Push Button Blood Collection Set	367338
BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367391
BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367392



BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367393
BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367363
BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367364
BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367365

The above products are manufactured by; **Becton, Dickinson and Company (BD)**, 1575 Airport Road, Sumter, SC 29153, USA; **BD Medical Systems Infusion Therapy Systems**, 9450 South State St., Sandy, UT 84070, USA, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Microtainer® Contact-Activated Lancet	366592
BD Microtainer® Contact-Activated Lancet	366593
BD Microtainer® Contact-Activated Lancet	366594

The above products are manufactured by; **HTL-STREFA S.A.**, Adamowek Street 7, 95-035 Ozorkow, Poland, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Vacutainer® Flashback Blood Collection Needle	301746
BD Vacutainer® Flashback Blood Collection Needle	301747
BD Vacutainer® Flashback Blood Collection Needle	301748

The above products are manufactured by; **Becton Dickinson Medical (S) Pte Ltd.**, 30 Tuas Avenue 2, Singapore, 639461, Singapore, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Vacutainer® Stretch Latex-Free Tourniquet	367204
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The above product is manufactured by; **Hygenic Corporation**, 1245 Home Avenue, Akron, OH 44310-2575, United States, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA





BD Vacutainer® Rapid Serum Tube (RST) Blood Collection Tubes Thrombin	368774
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The above products are manufactured by; **Tokuyama Sekisui Co., Ltd**, 4560 Kaisei-cho, Shunan City, Yamaguchi, 746-0006 Japan, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

BD Microtainer® Blood Collection Tube Holder	366270
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The above products are manufactured by; **Kabe Labortechnik GMBH**, 51588 Nümbrecht-Elsenroth, Germany, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

