



Medicines & Healthcare products  
Regulatory Agency

151 Buckingham Palace Road  
London SW1W 9SZ  
United Kingdom

[mhra.gov.uk](http://mhra.gov.uk)

**SAE 188/V6792/1**

**27/09/2016 10:37:51**

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

On behalf of the Department of Health

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

#### **VIETNAM**

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  
 Ordered on  
 Directive/Class  
 Mfr Name

ord-20160927-101241-xtjs  
 27/09/2016  
 98/79/EC  
 Becton, Dickinson and Company USA

#	Device Make	Device Model
1	BD Vacutainer® Luer-Lok™ Access Device Holder with Pre-Attached Multiple Sample Adapter	364902
2	BD Vacutainer® Blood Transfer Device Holder with Pre-Attached Multiple Sample Female Luer Adapter	364810
3	BD Microtainer® K2E Tubes	365975
4	BD Microtainer® Z Tubes	365964
5	BD Microtainer® LH Tubes	365966
6	BD Microtainer® SST™ Tubes	365968
7	BD Microtainer® SST™ Amber Tubes	365979
8	BD Microtainer® PST™ LH Tubes	365986
9	BD Microtainer® PST™ LH Amber Tubes	365988
10	BD Microtainer® FE Microcollection Tubes	365993
11	BD Microtainer® Quikheel™ Premie Lancet	368102
12	BD Microtainer® Quikheel™ Lancet	368103
13	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

14	BD Vacutainer® Z (No Additive) Plus Urine Tube	364938
15	BD Vacutainer® Urine Transfer Straw	364940
16	BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate Plus Urine Tube	364944
17	BD Vacutainer® Boric Acid Sodium Borate/Formate Plus C&S Urine Tube	364955
18	BD Vacutainer® Boric Acid Sodium Borate/Formate Plus C&S Urine Tube	364958
19	BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate Plus Urine Tube	364959
20	BD Vacutainer® Boric Acid, Sodium Formate For Urine Only 6ml 13x100m m	364969
21	BD Vacutainer® Urine Analysis Preservative Tube	364992
22	BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical	365000
23	BD Vacutainer® Urinalysis Preservative Plus Urine	365017
24	BD Vacutainer® Urinalysis Preservative Plus Urine Tube	368832
25	BD Microtainer® MAP Microtube for Automated Process K2 EDTA 1.0 mg	363706
26	BD Microtainer® MAP Microtube for Automated Process K2 EDTA 1.0 mg	363806
27	BD Vacutainer® Plus Blood Collection Tubes	364305





28	BD Vacutainer® 9NC 0.109M 0.2 ml Plus Blood Collection Tubes	368273
29	BD Vacutainer® Blood Collection Tubes 0.129M 9NC	368932
30	BD Vacutainer® FX 5mg 4mg Plus Blood Collection Tubes	368920
31	BD Vacutainer® FX 10mg 8mg Plus Blood Collection Tubes	368921
32	BD Vacutainer® FX 5mg 4mg Plus Tubes	367934
33	BD Vacutainer® FX 10mg:8mg Plus Blood Collection Tubes	367935
34	BD Vacutainer® Sodium HeparinN (NH) 33 USP = 33 IU Blood Collection Tubes	367671
35	BD Vacutainer® K2 EDTA (K2E) Plus Blood Collection Tubes	367862
36	BD Vacutainer® CPT™ NH: ~130 IU FICOLL™: 2.0mL	362780
37	BD Vacutainer® CPT™ NC: 0.45 ml FICOLL™: 1.0mL	362781
38	BD Vacutainer® CPT™ NC: 1.0mL FICOLL™: 2.0mL	362782
39	BD Vacutainer® PPT™ Plasma Preparation Tube K2E (EDTA) 9.0 mg	362791
40	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362794
41	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 9.0 mg	362795
42	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362799
43	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362800
44	BD Vacutainer® Thrombin Tubes	368922
45	BD Vacutainer® Thrombin Tubes	368923
46	BD Vacutainer® Thrombin Tubes	368925
47	BD Vacutainer® Trace Element Serum Plus Blood Collection Tubes	368380
48	BD Vacutainer® Trace Element K2 EDTA (K2E) Plus Blood Collection Tubes 10.8 mg	368381
49	BD Vacutainer® Trace Element Serum Plus Blood Collection Tubes	369627
50	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

51	BD Vacutainer® Multiple Sample Luer Adapter	367300
52	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368652
53	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368653



54	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368654
55	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368655
56	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367353
57	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367354
58	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367355
59	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367356
60	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	368657
61	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	368658
62	BD Vacutainer® Eclipse™ Blood Collection Needle	368609
63	BD Vacutainer® Eclipse™ Blood Collection Needle	368610
64	BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder	368650
65	BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder	368651
66	BD Vacutainer® SST™ Blood Collection Tubes	367782
67	BD Vacutainer® SST™ Plus Blood Collection Tubes	368825
68	BD Vacutainer® SST™ Plus Blood Collection Tubes	367985
69	BD Vacutainer® Serum / CAT Plus Blood Collection Tubes	367819
70	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

71	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

72	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365030
73	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365031
74	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365032





75	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365033
76	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365034
77	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365035
78	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365036
79	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365039
80	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365040
81	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365042
82	BD Vacutainer® 9NC 0.109M 0.2 ml Plus Blood Collection Tubes	368273
83	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

84	BD Vacutainer® Blood Collection Set	368382
85	BD Vacutainer® Blood Collection Set	368383
86	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

87	BD Vacutainer® Safety-Lok™ Blood Collection Set	360293
88	BD Vacutainer® Safety-Lok™ Blood Collection Set	360294
89	BD Vacutainer® Safety-Lok™ Blood Collection Set	360295
90	BD Vacutainer® Safety-Lok™ Blood Collection Set	367246
91	BD Vacutainer® Safety-Lok™ Blood Collection Set	367247
92	BD Vacutainer® Safety-Lok™ Blood Collection Set	367288
93	BD Vacutainer® Safety-Lok™ Blood Collection Set	367295
94	BD Vacutainer® Safety-Lok™ Blood Collection Set	368382
95	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



96	BD Vacutainer® Safety-Lok™ Blood Collection Set	367282
97	BD Vacutainer® Safety-Lok™ Blood Collection Set	367284
98	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

99	BD Vacutainer® Push Button Blood Collection Set	367323
100	BD Vacutainer® Push Button Blood Collection Set	367324
101	BD Vacutainer® Push Button Blood Collection Set	367326
102	BD Vacutainer® Push Button Blood Collection Set	367341
103	BD Vacutainer® Push Button Blood Collection Set	367342
104	BD Vacutainer® Push Button Blood Collection Set	367344
105	BD Vacutainer® Push Button Blood Collection Set	367335
106	BD Vacutainer® Push Button Blood Collection Set	367336
107	BD Vacutainer® Push Button Blood Collection Set	367338
108	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367391
109	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367392
110	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367393
111	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367363
112	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367364
113	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

114	BD Vacutainer® Flashback Blood Collection Needle	301746
115	BD Vacutainer® Flashback Blood Collection Needle	301747
116	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

117	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

118	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

119	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

120	BD Vacutainer™ 24 Hour Urine Specimen Container	364982
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The above products are manufactured by; **Viscot Medical LLC**, 32 West Street, East Hanover, NJ, 07936, USA, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

**End of schedule. No additional information past this point.**

