



Medicines & Healthcare products
Regulatory Agency

MHRA
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Canary Wharf
London
E14 4PU
United Kingdom
mhra.gov.uk

SAE 188/V14114/2

28/01/2019 13:19:36

**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**, 1 Becton Drive, NJ 07417-1880, Franklin Lakes, UNITED STATES OF AMERICA, 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,

Gbemisola Sunmon

Certificate of Free Sale Administration Team
Signed on Behalf of MHRA



Schedule of Devices requested for
 Ordered on
 Directive/Class
 Mfr Name

ord-20190128-130742-qmhb
 28/01/2019
 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 Tube	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® Blood Collection Tubes 0.129M 9NC	368932
28	BD Vacutainer® FX 5mg 4mg Plus Blood Collection Tubes	368920
29	BD Vacutainer® FX 10mg 8mg Plus Blood Collection Tubes	368921
30	BD Vacutainer® FX 5mg 4mg Plus Tubes	367934
31	BD Vacutainer® FX 10mg:8mg Plus Blood Collection Tubes	367935
32	BD Vacutainer® Sodium HeparinN (NH) 33 USP = 33 IU Blood Collection Tubes	367671
33	BD Vacutainer® K2 EDTA (K2E) Plus Blood Collection Tubes	367862



34	BD Vacutainer® CPT™ NH: ~130 IU FICOLL™: 2.0mL	362780
35	BD Vacutainer® CPT™ NC: 0.45 ml FICOLL™: 1.0mL	362781
36	BD Vacutainer® CPT™ NC: 1.0mL FICOLL™: 2.0mL	362782
37	BD Vacutainer® PPT™ Plasma Preparation Tube K2E (EDTA) 9.0 mg	362791
38	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362794
39	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 9.0 mg	362795
40	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362799
41	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362800
42	BD Vacutainer® Thrombin Tubes	368922
43	BD Vacutainer® Trace Element Serum Plus Blood Collection Tubes	368380
44	BD Vacutainer® Trace Element K2 EDTA (K2E) Plus Blood Collection Tubes 10.8 mg	368381
45	BD Vacutainer® Trace Element Serum Plus Blood Collection Tubes	369627
46	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		
47	BD Vacutainer® Multiple Sample Luer Adapter	367300
48	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368652



49	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368653
50	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367353
51	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367354
52	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367355
53	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367356
54	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	368657
55	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	368658
56	BD Vacutainer® Eclipse™ Blood Collection Needle	368609
57	BD Vacutainer® Eclipse™ Blood Collection Needle	368610
58	BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder	368650
59	BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder	368651
60	BD Vacutainer® SST™ Blood Collection Tubes	367782
61	BD Vacutainer® SST™ Plus Blood Collection Tubes	368825
62	BD Vacutainer® SST™ Plus Blood Collection Tubes	367985
63	BD Vacutainer® Serum / CAT Plus Blood Collection Tubes	367819
64	BD Vacutainer® Standard Yellow Holder	364879



65	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367391
66	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367392
67	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367393
68	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367363
69	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367364
70	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, 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
72	BD Vacutainer® Plus Blood Collection Tubes	364305

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

73	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365030
74	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365031
75	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365032
76	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365033
77	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365034
78	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365035
79	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365036



80	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365039
81	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365040
82	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365042
83	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365049
84	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365050
85	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365051
86	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365052
87	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365053
88	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365054
89	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365055
90	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365056
91	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365057
92	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365081
93	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365087
94	BD Vacutainer® 9NC 0.109M 0.2 ml Plus Blood Collection Tubes	368273

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

95	BD Vacutainer® Pronto™ Quick Release Needle Holder	368872
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The above product is 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



96	BD Vacutainer® Safety-Lok™ Blood Collection Set	360293
97	BD Vacutainer® Safety-Lok™ Blood Collection Set	360294
98	BD Vacutainer® Safety-Lok™ Blood Collection Set	360295
99	BD Vacutainer® Safety-Lok™ Blood Collection Set	367246
100	BD Vacutainer® Safety-Lok™ Blood Collection Set	367247
101	BD Vacutainer® Safety-Lok™ Blood Collection Set	367288
102	BD Vacutainer® Safety-Lok™ Blood Collection Set	367295
103	BD Vacutainer® Safety-Lok™ Blood Collection Set	368382
104	BD Vacutainer® Safety-Lok™ Blood Collection Set	368383
<p>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</p>		
105	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368654
106	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368655
<p>The above products are manufactured by; NIPRO MEDICAL INDUSTRIES LTD., Tatebayashi Plant, 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518, Japan; 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</p>		
107	BD Vacutainer® Safety-Lok™ Blood Collection Set	367282
108	BD Vacutainer® Safety-Lok™ Blood Collection Set	367284



109	BD Vacutainer® Safety-Lok™ Blood Collection Set	367286
<p>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</p>		
110	BD Vacutainer® Push Button Blood Collection Set	367323
111	BD Vacutainer® Push Button Blood Collection Set	367324
112	BD Vacutainer® Push Button Blood Collection Set	367326
113	BD Vacutainer® Push Button Blood Collection Set	367341
114	BD Vacutainer® Push Button Blood Collection Set	367342
115	BD Vacutainer® Push Button Blood Collection Set	367344
116	BD Vacutainer® Push Button Blood Collection Set	367335
117	BD Vacutainer® Push Button Blood Collection Set	367336
118	BD Vacutainer® Push Button Blood Collection Set	367338
<p>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</p>		
119	BD Vacutainer® Flashback Blood Collection Needle	301746
120	BD Vacutainer® Flashback Blood Collection Needle	301747
121	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

122	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

123	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

124	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

125	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

126	BD Vacutainer® Stretch Tourniquet	367198
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127	BD Vacutainer® Stretch Tourniquet	367209
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128	BD Vacutainer® Stretch Tourniquet	367205
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129	BD Vacutainer® Stretch Tourniquet	367199
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The above products are manufactured by; **Qidong Yongsheng Medical Supplies Factory**, No. 9, Yuelong East Road, Qidong Science and Technology Innovation Park, Nantong City, Jiangsu, 226200, P.R. China, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, 1 Becton Drive, Franklin Lakes, NJ 07417-1885, USA

End of schedule. No additional products past this point.

