



Medicines & Healthcare products
Regulatory Agency

151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

mhra.gov.uk

SAE 188/V11972/2

21/03/2018 09:48:34

Medicines and Healthcare Products Regulatory Agency

On behalf of the Department of Health

CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS TO

TAIWAN

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

ord-20180321-094721-bkyw

Ordered on

21/03/2018

Directive/Class

98/79/EC

Mfr Name

Becton, Dickinson and
Company USA

#	Device Make	Device Model
2	BD Vacutainer® Luer-Lok™ Access Device Holder with Pre-Attached Multiple Sample Adapter	364902
3	BD Vacutainer® Blood Transfer Device Holder with Pre-Attached Multiple Sample Female Luer Adapter	364810
4	BD Microtainer® K2E Tubes	365975
5	BD Microtainer® Z Tubes	365964
6	BD Microtainer® LH Tubes	365966
7	BD Microtainer® SST™ Tubes	365968
8	BD Microtainer® SST™ Amber Tubes	365979
9	BD Microtainer® PST™ LH Tubes	365986
10	BD Microtainer® PST™ LH Amber Tubes	365988
11	BD Microtainer® FE Microcollection Tubes	365993
12	BD Microtainer® Quikheel™ Premie Lancet	368102
13	BD Microtainer® Quikheel™ Lancet	368103
14	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		
15	BD Vacutainer® Z (No Additive) Plus Urine Tube	364938
16	BD Vacutainer® Urine Transfer Straw	364940
17	BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate Plus Urine Tube	364944
18	BD Vacutainer® Boric Acid Sodium Borate/Formate Plus C&S Urine Tube	364955
19	BD Vacutainer® Boric Acid Sodium Borate/Formate Plus C&S Urine Tube	364958



20	BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate Plus Urine Tube	364959
21	BD Vacutainer® Boric Acid, Sodium Formate For Urine Only 6ml 13x100m m	364969
22	BD Vacutainer® Urine Analysis Preservative Tube	364992
23	BD Vacutainer® Z (No Additive) Plus Urine Tube - Conical	365000
24	BD Vacutainer® Urinalysis Preservative Plus Urine Tube	365017
25	BD Vacutainer® Urinalysis Preservative Plus Urine Tube	368832
26	BD Microtainer® MAP Microtube for Automated Process K2 EDTA 1.0 mg	363706
27	BD Microtainer® MAP Microtube for Automated Process K2 EDTA 1.0 mg	363806
28	BD Vacutainer® Blood Collection Tubes 0.129M 9NC	368932
29	BD Vacutainer® FX 5mg 4mg Plus Blood Collection Tubes	368920
30	BD Vacutainer® FX 10mg 8mg Plus Blood Collection Tubes	368921
31	BD Vacutainer® FX 5mg 4mg Plus Tubes	367934
32	BD Vacutainer® FX 10mg:8mg Plus Blood Collection Tubes	367935
33	BD Vacutainer® Sodium HeparinN (NH) 33 USP = 33 IU Blood Collection Tubes	367671
34	BD Vacutainer® K2 EDTA (K2E) Plus Blood Collection Tubes	367862
35	BD Vacutainer® CPT™ NH: ~130 IU FICOLL™: 2.0mL	362780
36	BD Vacutainer® CPT™ NC: 0.45 ml FICOLL™: 1.0mL	362781
37	BD Vacutainer® CPT™ NC: 1.0mL FICOLL™: 2.0mL	362782
38	BD Vacutainer® PPT™ Plasma Preparation Tube K2E (EDTA) 9.0 mg	362791
39	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362794



40	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 9.0 mg	362795
41	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362799
42	BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg	362800
43	BD Vacutainer® Thrombin Tubes	368922
44	BD Vacutainer® Thrombin Tubes	368923
45	BD Vacutainer® Thrombin Tubes	368925
46	BD Vacutainer® Trace Element Serum Plus Blood Collection Tubes	368380
47	BD Vacutainer® Trace Element K2 EDTA (K2E) Plus Blood Collection Tubes 10.8 mg	368381
48	BD Vacutainer® Trace Element Serum Plus Blood Collection Tubes	369627
49	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		
50	BD Vacutainer® Multiple Sample Luer Adapter	367300
51	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368652
52	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368653
53	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367353
54	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367354
55	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367355
56	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	367356
57	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	368657



58	BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder	368658
59	BD Vacutainer® Eclipse™ Blood Collection Needle	368609
60	BD Vacutainer® Eclipse™ Blood Collection Needle	368610
61	BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder	368650
62	BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder	368651
63	BD Vacutainer® SST™ Blood Collection Tubes	367782
64	BD Vacutainer® SST™ Plus Blood Collection Tubes	368825
65	BD Vacutainer® SST™ Plus Blood Collection Tubes	367985
66	BD Vacutainer® Serum / CAT Plus Blood Collection Tubes	367819
67	BD Vacutainer® Standard Yellow Holder	364879

The above products are manufactured by; **Becton, Dickinson and Company (BD)**, 1575 Airport Road, Sumter, SC 29153, USA

68	BD Vacutainer® Urine Collection Cups	364941
69	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, and **Becton, Dickinson and Company**, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom

70	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365030
71	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365031
72	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365032
73	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365033



74	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365034
75	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365035
76	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365036
77	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365039
78	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365040
79	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365042
80	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365049
81	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365050
82	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365051
83	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365052
84	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365053
85	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365054
86	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365055
87	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365056
88	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365057
89	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365081
90	BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes	365087
91	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		
92	BD Vacutainer® Pronto™ Quick Release Needle Holder	368872



The above product is manufactured by; **NIPRO MEDICAL INDUSTRIES LTD.**, Tatebayashi Plant, 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518, Japan

93	BD Vacutainer® Safety-Lok™ Blood Collection Set	360293
94	BD Vacutainer® Safety-Lok™ Blood Collection Set	360294
95	BD Vacutainer® Safety-Lok™ Blood Collection Set	360295
96	BD Vacutainer® Safety-Lok™ Blood Collection Set	367246
97	BD Vacutainer® Safety-Lok™ Blood Collection Set	367247
98	BD Vacutainer® Safety-Lok™ Blood Collection Set	367288
99	BD Vacutainer® Safety-Lok™ Blood Collection Set	367295
100	BD Vacutainer® Safety-Lok™ Blood Collection Set	368382
101	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

102	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368654
103	BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder	368655

The above products are manufactured by; **NIPRO MEDICAL INDUSTRIES LTD.**, Tatebayashi Plant, 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518, Japan, and **Becton, Dickinson and Company (BD)**, 1575 Airport Road, Sumter, SC 29153, USA

104	BD Vacutainer® Safety-Lok™ Blood Collection Set	367282
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105	BD Vacutainer® Safety-Lok™ Blood Collection Set	367284
106	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</p>		
107	BD Vacutainer® Push Button Blood Collection Set	367323
108	BD Vacutainer® Push Button Blood Collection Set	367324
109	BD Vacutainer® Push Button Blood Collection Set	367326
110	BD Vacutainer® Push Button Blood Collection Set	367341
111	BD Vacutainer® Push Button Blood Collection Set	367342
112	BD Vacutainer® Push Button Blood Collection Set	367344
113	BD Vacutainer® Push Button Blood Collection Set	367335
114	BD Vacutainer® Push Button Blood Collection Set	367336
115	BD Vacutainer® Push Button Blood Collection Set	367338
116	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367391
117	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367392
118	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367393
119	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367363
120	BD Vacutainer® UltraTouch™ Push Button Blood Collection Set	367364
121	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, and **BD Medical Systems Infusion Therapy Systems**, 9450 South State St., Sandy, UT 84070, USA

122	BD Vacutainer® Flashback Blood Collection Needle	301746
123	BD Vacutainer® Flashback Blood Collection Needle	301747
124	BD Vacutainer® Flashback Blood Collection Needle	301748
125	The above products are manufactured by; Becton Dickinson Medical	
126	BD Vacutainer® Stretch Latex Free Tourniquet	367204

The above product is manufactured by; **Hygenic Corporation**, 1245 Home Avenue, Akron, OH 44310-2575, United States

127	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

128	BD Microtainer® Blood Collection Tube Holder	366270
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The above products are manufactured by; **Kabe Labortechnik GMBH**, 51588 Nümbrecht-Elsenroth, Germany

129	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

End of schedule. No additional products past this point.

