



Medicines & Healthcare products  
Regulatory Agency

151 Buckingham Palace Road  
London SW1W 9SZ  
United Kingdom

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

**SAE 188/V6223/2**

**27/07/2016 13:33:52**

## **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**, 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-20160727-133219-fpxs  
 27/07/2016  
 98/79/EC  
 Becton, Dickinson and Company

Device Make	Device Model
BD Vacutainer® EST Z (No Additive) Plus Blood Collection Tubes	362725
BD Vacutainer® CAT Plus Blood Collection Tubes	362080
BD Vacutainer® CAT Plus Blood Collection Tubes	362081
BD Vacutainer® CAT Plus Blood Collection Tubes	362082
BD Vacutainer® CAT Plus Blood Collection Tubes	362091
BD Vacutainer® CAT Plus Blood Collection Tubes	362092
BD Vacutainer® CAT Plus Blood Collection Tubes	364660
BD Vacutainer® SERUM/ CAT Plus Blood Collection Tubes	365904
BD Vacutainer® CAT Plus Blood Collection Tubes	367837
BD Vacutainer® CAT Plus Blood Collection Tubes	367895
BD Vacutainer® CAT (Clot Activator Tube) Plus Blood Collection Tubes	367896
BD Vacutainer® CAT (Clot Activator Tube) Plus Blood Collection Tubes	368271
BD Vacutainer® CAT (Clot Activator Tube) Plus Blood Collection Tubes	368492
BD Vacutainer® CAT Plus Blood Collection Tubes	368493
BD Vacutainer® CAT Plus Blood Collection Tubes	368813
BD Vacutainer® CAT Plus Blood Collection Tubes	368814
BD Vacutainer® CAT (Clot Activator Tube) Plus Blood Collection Tubes	368815
BD Vacutainer® CAT Plus Blood Collection Tubes	368817
BD Vacutainer® CAT Plus Blood Collection Tubes	368863
BD Vacutainer® CAT Plus Blood Collection Tubes	368975
BD Vacutainer® CAT (Clot Activator Tube) Plus Blood Collection Tubes	369032
BD Vacutainer® CAT Plus Blood Collection Tubes	369625
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	365301
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	365302
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	365317
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	365327
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	365328
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	366127
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	366444
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	366468
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	366566
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	366644
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	366880
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	362074
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	362075
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	362090
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	366881
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	362076



BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	362077
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	362079
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	362078
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	366882
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	367953
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	367954
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	367955
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	367956
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	367957
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	367958
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	368498
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	368879
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	368965
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	368966
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	368967
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	368968
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	368969
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes	368970
BD Vacutainer® SST™ II Advance Blood Collection Tubes	365072
BD Vacutainer® SST™ II Advance Blood Collection Tubes	365074
BD Vacutainer® Thrombin Plus Blood Collection Tubes	367811
BD Vacutainer® Thrombin Plus Blood Collection Tubes	367817
BD Vacutainer® NH (Sodium Heparin) 68 I.U. Plus Blood Collection Tubes	367869
BD Vacutainer® NH 68 I.U. Plus Blood Collection Tubes	369623
BD Vacutainer® NH (Sodium Heparin) 102 I.U. Plus Blood Collection Tubes	367876
BD Vacutainer® LH 68 I.U. Plus Blood Collection Tubes	365308
BD Vacutainer® NH 102 I.U. Plus Blood Collection Tubes	369622
BD Vacutainer® LH 170 I.U. Plus Blood Collection Tubes	367526
BD Vacutainer® LH 68 I.U. Plus Blood Collection Tubes	367883
BD Vacutainer® LH 102 I.U. Plus Blood Collection Tubes	367885
BD Vacutainer® LH 34 I.U. Plus Blood Collection Tubes	368272
BD Vacutainer® LH (Lithium Heparin) 34 I.U. Plus Blood Collection Tubes	368494
BD Vacutainer® LH 34 I.U. Plus Blood Collection Tubes	368495
BD Vacutainer® LH 68 I.U. Plus Blood Collection Tubes	368496
BD Vacutainer® LH (Lithium Heparin) 68 I.U. Plus Blood Collection Tubes	368884
BD Vacutainer® LH (Lithium Heparin) 102 I.U. Plus Blood Collection Tubes	368886
BD Vacutainer® LH 102 I.U. Plus Blood Collection Tubes	368889
BD Vacutainer® LH PST™ II Plus Blood Collection Tubes	365321
BD Vacutainer® LH PST™ II Plus Blood Collection Tubes	366567
BD Vacutainer® LH PST™ II Plus Blood Collection Tubes	367373
BD Vacutainer® LH PST™ II Plus Blood Collection Tubes	367374
BD Vacutainer® LH PST™ II Plus Blood Collection Tubes	367375
BD Vacutainer® LH (Lithium Heparin) PST™ II Plus Blood Collection Tubes	367376
BD Vacutainer® LH PST™ II Plus Blood Collection Tubes	367377



BD Vacutainer® LH (Lithium Heparin) PST™ II Plus Blood Collection Tubes	367378
BD Vacutainer® LH PST™ II Plus Blood Collection Tubes	368497
BD Vacutainer® FX 12.5mg/10mg Plus Blood Collection Tubes	368201
BD Vacutainer® NaF 3.0mg Na <sub>2</sub> EDTA 6.0mg Plus Blood Collection Tubes	368520
BD Vacutainer® NaF 6.0mg Na <sub>2</sub> EDTA 12.0mg Plus Blood Collection Tubes	368521
BD Vacutainer® NaF 6.0mg Na <sub>2</sub> EDTA 12.0mg Plus Blood Collection Tubes	365305
BD Vacutainer® 9NC 0.109M Buffered Trisodium Citrate Plus Blood Collection Tubes	363047
BD Vacutainer® 9NC 0.109M Buffered Trisodium Citrate Plus Blood Collection Tubes	363048
BD Vacutainer® 9NC 0.129M Plus Blood Collection Tubes	363079
BD Vacutainer® 9NC 0.109M Plus Blood Collection Tubes	363093
BD Vacutainer® 9NC 0.129M Plus Blood Collection Tubes	363097
BD Vacutainer® 9NC 109M Plus Blood Collection Tubes	365303
BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	365300
BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	368834
BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	365329
BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	365330
BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	365331
BD Vacutainer® K2E 18.0mg Plus Blood Collection Tubes	365312
BD Vacutainer® K2E 7.2mg Plus Blood Collection Tubes	365314
BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	365900
BD Vacutainer® K2E (EDTA) 18.0mg Plus Blood Collection Tubes	367525
BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	367838
BD Vacutainer® K2E 18.0mg Plus Blood Collection Tubes	367386
BD Vacutainer® K2E 7.2mg Plus Blood Collection Tubes	367839
BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	367864
BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	362089
BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	367873
BD Vacutainer® K2E 10.8mg Plus Blood Collection Tubes	367950
BD Vacutainer® K2E 18.0mg Plus Blood Collection Tubes	368267
BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	368274
BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	368499
BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	368841
BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	362083
BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	362084
BD Vacutainer® K2E (EDTA) 3.6mg Plus Blood Collection Tubes	364661
BD Vacutainer® K2E 3.6mg Plus Blood Collection Tubes	368843
BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	368856
BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	362072
BD Vacutainer® K2E 5.4mg Plus Blood Collection Tubes	362085
BD Vacutainer® K2E (EDTA) 5.4mg Plus Blood Collection Tubes	364664



BD Vacutainer® K2E (EDTA) 7.2mg Plus Blood Collection Tubes	368861
BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	367836
BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	362086
BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	362087
BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	364663
BD Vacutainer® K3E 3.6mg Plus Blood Collection Tubes	367858
BD Vacutainer® K3E 7.2mg Plus Blood Collection Tubes	368270
BD Vacutainer® K3E 5.4mg Plus Blood Collection Tubes	368857
BD Vacutainer® K3E 5.4mg Plus Blood Collection Tubes	362073
BD Vacutainer® K3E 5.4mg Plus Blood Collection Tubes	362088
BD Vacutainer® K3E 5.4mg Plus Blood Collection Tubes	364662
BD Vacutainer® K3E 7.2mg Plus Blood Collection Tubes	368860
BD Vacutainer® K3E 10.8mg Plus Blood Collection Tubes	366547
BD Vacutainer® K2E 7.2mg Plus Blood Collection Tubes	366164
BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	367941
BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	367924
BD Vacutainer® K2E (EDTA) 10.8mg Plus Blood Collection Tubes	367978
BD Vacutainer® Z (No Additive) Plus Urine Tube	364915
BD Vacutainer® Z (No Additive) Plus Urine Tube	364917
BD Vacutainer® Z (No Additive) Plus Urine Tube	368831
BD Vacutainer® Z (No Additive) Plus Urine Tube	364918
BD Vacutainer® Z (No Additive) Plus Urine Tube	365307
BD Vacutainer® Z (No Additive) Plus Urine Tube	365309
BD Vacutainer® Z (No Additive) Plus Urine Tube	365318
BD Vacutainer® Z (No Additive) Plus Urine Tube	368500
BD Vacutainer® Z (No Additive) Plus Urine Tube	368501
BD Vacutainer® Glass Serum tube	366684
BD Vacutainer® Z Blood Collection Tubes	367614
BD Vacutainer® Z 7 ml 13x100mm	367615
BD Vacutainer® Z Blood Collection Tubes	367624
BD Vacutainer® Z 10 ml 16x100mm	368430
BD Vacutainer® Z 5 ml 13x75mm	368434
BD Vacutainer® NH (Sodium Heparin) 170 I.U. Blood Collection Tubes	368480
BD Vacutainer® NH 119I.U. Blood Collection Tubes	367735
BD Vacutainer® 9NC 0.105M 6 ml 13x100mm	366575
BD Vacutainer® 9NC 0.129M Plus Blood Collection Tubes	366646
BD Vacutainer® 9NC 0.5 ml 0.105M Blood Collection Tubes	367691
BD Vacutainer® 9NC 0.129M Blood Collection Tubes	367704
BD Vacutainer® 9NC 0.5 ml 0.105M Buffered Trisodium Citrate Blood Collection Tubes	367714
BD Vacutainer® ACD-A 1.5 ml Blood Collection Tubes	366645
BD Vacutainer® ACD-B Blood Collection Tubes	365319
BD Vacutainer® ACD-B 1.0ml Acid Citric Dextrose Solution B Blood Collection Tubes	367756
BD Vacutainer® CTAD Blood Collection Tubes	367562



BD Vacutainer® CTAD (Buffered Sodium Citrate Theophylline Adenosine Dipyridamole) Blood Collection Tubes	367599
BD Vacutainer® LH 60 I.U. L Iodoacetate 1.5mg Blood Collection Tubes	367748
BD Vacutainer® LH 100 I.U. L Iodoacetate 2.5mg Blood Collection Tubes	367749
BD Vacutainer® FH 20mg .143 I.U. Blood Collection Tubes	367764
BD Vacutainer® K3E 15% Aprotinin 250 KIU Blood Collection Tubes	361017
BD Vacutainer® K3E 15% Aprotinin 250 KIU Blood Collection Tubes	369629
BD Vacutainer® K3E 7.5% 0.072 ml 3 ml 13x17mm	367652
BD Seditainer™ 4NC 0.105M 1.26 ml Blood Collection Tubes	366666
BD Seditainer™ 4NC 0.105M 1.26 ml Blood Collection Tubes	366671
BD Seditainer™ 4NC 0.105M Blood Collection Tubes	366673
BD Seditainer™ 4NC 0.105M 1.26 ml Blood Collection Tubes	366674
BD Seditainer™ 4NC 0.105M 0.45 ml Blood Collection Tubes	366676
BD Seditainer™ 4NC 0.105M 1.26 ml Blood Collection Tubes	366690
BD Vacutainer® 4NC 0.129M 0.4 ml Blood Collection Tubes	367740
BD Vacutainer® 4NC 0.129M Blood Collection Tubes	367741
BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360210
BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360211
BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360212
BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360213
BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360214
BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360215
BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder	368835
BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder	368836
BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle	368837
BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle	368838
BD Preset™ Arterial Blood Collection Syringe	364316
BD Preset™ Arterial Blood Collection Syringe	364416
BD A-Line™ Arterial Blood Collection Syringe	364356
BD A-Line™ Arterial Blood Collection Syringe	364376
BD A-Line™ Arterial Blood Collection Syringe	364378
BD Preset™ Arterial Blood Collection Syringe	364314
BD Preset™ Arterial Blood Collection Syringe	364327
BD Preset™ Arterial Blood Collection Syringe	364413
BD Preset™ Arterial Blood Collection Syringe	364415
BD Preset™ Eclipse™ Arterial Blood Collection Syringe	364389
BD Preset™ Eclipse™ Arterial Blood Collection Syringe	364390
BD Preset™ Eclipse™ Arterial Blood Collection Syringe	364391
BD Preset™ Eclipse™ Arterial Blood Collection Syringe	364393

The above products are manufactured by; **Becton, Dickinson and Company**, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom, as the Legal Manufacturer.



BD Vacutainer® NaF 3.0mg N2E 6.0mg Plus Blood Collection Tubes	367933
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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**, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom

BD Vacutainer® 9NC 0.109M Plus Blood Collection Tubes	363095
BD Vacutainer® One Use Holder	364815

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BD Sedi-20	361545
BD Sedi-40	361546

The above products are manufactured by; **ELITech Group B.V.**, Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom

BD Sentry™ Safety Lancet	369528
BD Sentry™ Safety Lancet	369523

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**, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom

BD Seditainer™ Stand	366016
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The above products are manufactured by; **SMT**, 6 Rue Belmont, BP 1002, 01101, Oyonnax, on behalf of the Legal Manufacturer; **Becton, Dickinson and Company**, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom

