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Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI
E DEL SERVIZIO FARMACEUTICO
Uff. 3 - ex DGFDMD

DGDMF/III/P/I.5.I.e.1/2015/671

VISTA la direttiva 93/42/CEE concernente i dispositivi medici;

HAVING REGARD to Directive 93/42/EEC concerning medical devices;

VISTO il Decreto Legislativo n.46/97 e successive modifiche recante il recepimento della direttiva 93/42/CEE;

HAVING REGARD to the Legislative Decree n. 46/97 and its following amendments implementing Directive 93/42 EEC;

VISTA la richiesta con prot. 58485- A- 03/12/2015 presentata dalla ditta **Bioteck S.p.A.**, con sede legale in Via Enrico Fermi 49, 36057 Arcugnano (VI), Italia, P. Iva 02702750247;

HAVING REGARD to the request ref. 58485-A-03/12/2015, submitted by the Company **Bioteck S.p.A.**, located in Via Enrico Fermi 49, 36057 Arcugnano (VI), Italy, VAT number 02702750247;

CONSIDERATO che la ditta ha effettuato i versamenti richiesti dal D.M. 07 Agosto 2012;

WHEREAS the Company paid the fees required by Ministerial Decree August 7th, 2012;

VISTI gli atti d'ufficio;

HAVING REGARD TO the official deeds;

**SI ATTESTA
IT IS ATTESTED**

che la Ditta **Bioteck S.p.A.**, con sede legale in Via Enrico Fermi 49, 36057 Arcugnano (VI), Italia, con sito di produzione in Via Giovanni Agnelli 3, 10020 Riva presso Chieri (TO), Italia, è il fabbricante e ha marcato CE come dispositivi medici, secondo le procedure previste dalla direttiva 93/42 CEE, i seguenti prodotti:

*that according to Directive 93/42 EEC, the Company **Bioteck S.p.A.**, located in Via Enrico Fermi 49, 36057 Arcugnano (VI), Italy, with manufacturing plant in Bioteck S.p.A., Via Giovanni Agnelli 3, 10020 Riva presso Chieri (TO), Italy, is the manufacturer and has marked CE as medical devices, the following products:*

Nome dispositivo Device name	BIOCOLLAGEN®/ COVER®/ HEART® BIO-GEN® OSTEOPLANT® / OSTEOXENON® / PLASTBONE® / CALCITOS AWAYR® /3 SYNT®/
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Codici/Codes

BIOCOLLAGEN

BCG-01; BCG-01n; BCG-02; BCG-03; BCG-04; BCG-05; BCG-06; BCG-07; BCG-07e; BCG-08; BCG-09; BCG-10; BCG-12; BCG-14; BCG-16; BCG-18; BCG-20; BCG-22; BCG-100; BCG-200; BCG-500; BCG-PLG1; BCG-PLG2; BCG-PLG3; BCG-1008; BCG-255;

BCG-508; BCG-CRU1; BCG-CRU2; BCG-CRU3; BCG-CRU4; BCG-CRU10; BCG-CRU10j; BCG-CRU15; BCG-CRU5; BCG-CRU20; BCG-GEL025; BCG-GEL05; BCG-GEL1; BCG-GEL10; BCG-GEL15; BCG-GEL1n; BCG-GEL2; BCG-GEL3; BCG-GEL4; BCG-GEL20; BCG-GEL430; BCG-GEL5; BCG-GEL6; BCG-GEL7; BCG-GEL8; BCG-merg; BCG-mergDisc; BCG-mergS; BCG-mergK; BCG-mergSK; BCG-mergQ; BCG-mergSQ; BCG-mergW; BCG-mergSW; BCG-mergY; BCG-XC40; BCG-XC01; BCG-XC05; BCG-XC30; BCG-XC10; BCG-XC20; BCG-XC50; BCG-XC60.

COVER

CVR-01; CVR-02; CVR-05; CVR-10; CVR-20; CVR-GEL1; CVR-GEL5; CVR-GEL10; CVR-GEL15; CVR-GEL20.

BIO-GEN

BGB-10; BGB-11; BGB-12; BGB-15; BGB-20; BGB-25; BGB-30; BGB-40; BGC-04; BGC-05; BGC-05n; BGC-10; BGC-12; BGC-14; BGC-16; BGC-18; BGC-20; BGC-22; BGC-24; BGM-MIX; BGM-05; BGM-05n; BGM-10; BGM-20; BGM-30; BGM-35; BGM-40; BGM-50; BGM-100; BGM-GEL025; BGM-GEL05; BGM-GEL1; BGM-GEL1n; BGM-GEL2; BGM-GEL5; BGM-GEL10; BGM-GEL15; BGM-GEL20; BGM-GEL30; BGP-01; BGP-01n; BGP-02; BGP-03; BGP-05; BGP-06; BGP-07; BGP-08; BGP-09; BGP-10; PGS01; PGS05; BGS-05; BGS-05n; BGS-08; BGS-09; BGS-10; BGS-11; BGS-15; BGS-20; BGS-21; BGS-22; BGS-23; BGS-24; BGS-25; BGS-30; BGS-40; BGS-50.

OSTEOPLANT


OSP-0452; OSP-0452A; OSP-0456; OSP-0456A; OSP-0460; OSP-0460A; OB-01-05; OB-01-10; OB-01-100; OB-01-20; OB-01-25; OB-01-30; OB-01-35; OB-01-40; OB-01-50; OB-01-55; OB-01-90; OB-02-08; OB-02-20; OB-02-01; OB-02-02; OB-02-03; OB-02-04; OB-02-05; OB-02-06; OB-02-07; OB-02-08; OB-02-09; OB-02-10; OB-02-20; OGM-GEL1; OGM-GEL10; OGM-GEL15; OGM-GEL2; OGM-GEL20; OGM-GEL5; OGM-GEL25; OGM-GEL30; OGS-03A; OGS-05A; OGS-AC10; OGS-AC20; OGS-AC25; OGS-AC5; OGS-AC30; OGS-AC40; OGS-AC50; OGS-ACI10; OGS-ACI5; OGS-ACI1; OGS-ACI2; OGS-ACI20; OGS-ACI30; OGS-ACI40; OGS-ACM10; OGS-ACM2; OGS-ACM5; OGS-ACM1; OGS-ACM20; OGS-ACM30; OGS-ACM40; OGS-ACM100; OGS-ACM200; OGS-ACM300; OGS-ACM400; OGS-ACM500; OGS-ACM600; OGS-ACI100; OGS-ACI200; OGS-ACI300; OGS-ACI400; OGS-ACI500; OGS-ACI600; OGS-ACX1; OGS-ACX2; OGS-ACX5; OGS-ACX10; OGS-ACX20; OGS-ACX30; OGS-ACX40; OGS-GEL1; OGS-GEL2; OGS-GEL5; OGS-GEL10.

CALCITOS

OMC-03; OMC-030; OMC-04; OMC-05; OMC-05S; OMC-10d; OMC-12S; OMC-15d; OMC-20d; OMC-25d; OMC-30d; OMC-E1; OMC-E2; OMC-40; OMC-50; OMC-60; OMC-70; OMC-80; OSP-01; OSP-010P; OSP-0125P; OSP-01A; OSP-01B; OSP-01B2; OSP-02; OSP-02B; OSP-03; OSP-04; OSP-05; OSP-05B; OSP-06; OSP-06B; OSP-07; OSP-070; OSP-075P; OSP-07A; OSP-08; OSP-09; OSP-10; OSP-11; OSP-12; OSP-20B; OSP-22; OSP-30; OSP-40; OSP-50; OSP-60; OSP-70; OSP-80; OSP-90; OSP-100; OSP-FIX2; OSP-FIX3.

OSTEOXENON

OSP-OX01; OSP-OX02; OSP-OX03; OSP-OX04; OSP-OX05; OSP-OX05R; OSP-OX06; OSP-OX07; OSP-OX08; OSP-OX09; OSP-OX10; OSP-OX11; OSP-OX12; OSP-OX13; OSP-OX14; OSP-OX15; OSP-OX21; OSP-OX22; OSP-OX23; OSP-OX24; OSP-OX25; OSP-OX30; OSP-OX31; OSP-OX32; OSP-OX33; OSP-OX34; OSP-OX35; OSP-OX36; OSP-OX37; OSP-OX38; OSP-OX39; OSP-OX40; OSP-OX41; OSP-OX50; OSP-OX51; OSP-OX52; OSP-OX53; OSP-OX54; OSP-OX55; OSP-OX60; OSP-OX61; OSP-OX62; OSP-OX63; OSP-OX64; OSP-OX65; OSP-OXAB1; OSP-OXAB2; OSP-OXAB5; OSP-OXAB10; OSP-S10f; OSP-S15f; OSP-S19f; OSP-S20f; OSP-S21f; OSP-S22f; OSP-S23f; OSP-S25f; OTC-C1; OTC-C2; OTC-C3; OTC-C4; OTC-C5; OTC-C6; OTC-C7; OTC-C8;



OTC-C9; OTC-C10; OTC-C15; OTC-C100; OTC-C200; OTC-C300; OTC-C400; OTC-C500; OTC-CE; OTC-CE2; OTC-CE5; OTC-S1; OTC-S10; OTC-S12; OTC-S12f; OTC-S13f; OTC-S2; OTC-S3; OTC-S4; OTC-S5; OTC-S5d; OTC-S7; OTC-S8; OTC-S9; OTC-S15; OTC-S20; OTC-S25; OTC-S30; OTC-S100; OTC-S200; OTC-S300; OTC-S400; OTC-S500.

PLASTBONE

PLB-01; PLB-02; PLB-03; PLB-04; PLB-06; PLB-01; PLB-05; PLB-07; PLB-08; PLB-09; PLB-10; PLB-20; PLB-30; PLB-40; PLB-50; PLB-GEL1; PLB-GEL2; PLB-GEL5; PLB-GEL10.

HEART

HRT-001; HRT-002; HRT-003; HRT-004; HRT-005; HRT-010; HRT-015; HRT-020; HRT-021; HRT-022; HRT-023; HRT-024; HRT-025; HRT-026; HRT-027; HRT-028; HRT-029; HRT-40DM; HRT-41DM; HRT-42DM; HRT-43DM; HRT-44DM; HRT-40EQ; HRT-41EQ; HRT-42EQ; HRT-43EQ; HRT-44EQ; HRT-40PC; HRT-41PC; HRT-42PC; HRT-43PC; HRT-44PC; HRT-45DM; HRT-50DM; HRT-55DM; HRT-60DM; HRT-65DM; HRT-70DM; HRT-60WM; HRT-61WM; HRT-62WM; HRT-63WM; HRT-64WM; HRT-65WM; HRT-66WM; HRT-67WM; HRT-68WM.

AWAYR

AWYR 20; AWYR 30; AWYR 40; AWYR 50; AWYR 60; AWYR 70; AWYR 80; AWYR 90.

3 SYNT

SY-G05; SY-G05n; SY-G10; SY-G10n; SY-G20; SY-G20n ; SY-M05; SY-M05n; SY-M10; SY-M10n; SY-M20; SY-M20n.

Tali prodotti, in base all'art.4 della citata direttiva, sono di libera circolazione e possono essere immessi in commercio in Italia e in tutto il territorio dell'Unione Europea.

The above mentioned products, according to the art. 4 of the Directive 93/42/EEC, can freely circulate and can be placed on the market in Italy and all over the European Union.

Questo documento è rilasciato in unico originale a richiesta del fabbricante ai fini di esportazione di dispositivi medici **al di fuori della Unione Europea.**

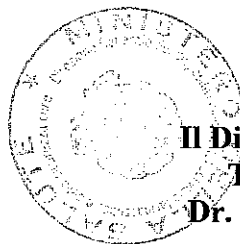
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**Il Direttore dell'Ufficio
The Office Manager
Dr. Annamaria Donato**

DP