ORLIMAN S.L.U.
Orthopedic Devices
C/ Ausias March, nº 3 – Pol. Ind. La Pobla – L´Eliana
46185 LA POBLA DE VALLBONA (Valencia) - ESPAÑA

EC DECLARATION OF CONFORMITY

Council Directive 93/42/EEC concerning Medical Devices / ANNEX VII
(As amended by Council Directive 2007/47/EC)

Mr. Enric Florensa Ortiz, in his name and representation of the manufacturer ORLIMAN S.L.U., with V.A.T. number: B-96122510, with number **SPANISH MEDICAL DEVICE OPERATION LICENSE 20-PS**, addressed in C/Ausias March, nº 3 – Polígono Industrial La Pobla de Vallbona – L´Eliana, 46185 La Pobla de Vallbona, Valencia, SPAIN;

DECLARES: that the medical devices described below, whose corresponding technical documentation is in my possession, meet the essential requirements set out in Directive Annex I which apply to it, therefore when used under the conditions and for the intended purposes, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other people.

CLASSIFICATION: Class I (Rule 1)

REFERENCES:

1000, 1001, 1001R, 1002, 1002R, 1003, 1004, 1004A, 1004R, 1005, 1005R, 1007, 1008, 1009, 1010, 1010R, 1011, 1012, 1013, 1014, 1015, 1016, 1017, 1018, 1100, 1100R, 1101, 1102, 1103, 1104, 1200, 1201, 1202, 1203, 1204, 1205, 1206, 1207, 1300, 1310, 1SSD, 1SSI, 2000-S, 2010-S, 2020-S, 2030-S, 2040-S, 2050-S, 2SSD, 2SSI, 3000-C, 3010-C, 3020-C, 3030-C, 3040-C, 3050-C, 4100, 4101, 4101-SP, 4102, 4103, 4103-A, 4104, 4104-A, 4105, 4106, 4107, 4108, 4109, 4110, 4111, 4112, 4113, 4115, 4116, 4119, 4200, 4201, 4202, 4203, 4204, 4205, 4300, 4301, 4302, 4303, 4304, 4400, 4401, 4402, 4403, 4404, 4405, 4406, 4500, 4600, 4601, 4602, 4603, 4604, 4607, 4700, 4701, 4702, 4800, 4801, 4802, 4803, 5100, 5101, 5102, 5103, 5103-A, 5104, 5104-A, 5105, 5106, 5107, 5108, 5109, 5111, 5112, 5113, 5115, 5116, 5201, 5202, 5203, 5300, 5301, 5302, 5303, 5400, 5401, 5402, 5403, 5404, 5500, 5501, 5502, 5600, 5601, 5602, 5603, 5604, 5700, 5701, 5800, 5801, 5802, 5803, 6102, 6103, 6103-A, 6104, 6104-A, 6112, 6113, 6119, 6120, 6121D, 6121I, 6211, 6212, 6213, 6214, 6215, 7102, 7103, 7103-A, 7104, 7104-A, 7112, 7113, 7113-A, 7117D, 7117I, 7119, 7120, 8102, 8103, 8104, 8105, 8106, 8107, 8301, 8401, 9104, 9105, 9106, 9107, 9201, 9202, 9203, 9301, 9401, 94230, 94231, 94240, 94250, 94251, 94260, 94261, 94300, 94301D, 94301I, 94302D, 94302I, 94303D, 94303I, 94304D, 94304I, A-130, A-131, A-132, AB01, AB02, AB10, AB11, AB12D, AB12I, AB13, AB14, AB20, AB22D, AB22I, AB24, AL070, AW01, B-110, B-150, B-155, BB-100, BE-080, BE-160, BE-162D, BE-162I, BE-165, BE-170, BE-175, BE-240, BE-240A, BE-240R, BE-245, BE-280, BE-300, BE-305, BEB-240, BH-110, BOD-100, BOD-100T, BOD-100TV, BOD-100TVL, BS-110, C-40, C-40N, C-41, C-42A, C-42B, C-43A, C-44, C-45, C-46, C-47, C-48, CC2106, CC2108, CC2109, CC2111, CC2206, CC2208, CC2209, CC2211, CC2300, CC2400, CC2503, CC2504, CC2600, CC2700, CC2701, CC2800, CEB-400, CEN-410, CINCHA-C42A, CINCHA-C42B, CINCHA-VAL, CJ100, COL-160, COL-165, COL-167, COL-169, COL-240, COL-245, COL-247, COL-249, COR-PL-BLANCO, COR-VL-2P-BE, COR-VL-2P-NEG, COR-VL-BEIGE, COR-VL-NEGRO, CP01, CP02, CP03, CP04, CT1001, CT1002, D-111, D-150, D-155, DH-111, DS01, DS02, DS03, DS04, DS05, DS06, DS07, E-240, E-241, EP-20A, EP-20B, EP-21G, EP-21V, EST-080, EST-082, EST-083, EST-084, EST-085, EST-086, EST-087, EST-088, EST-089, EST-090, EST-091D, EST-091I, ET-210, EV-100, EV-101, EV-200, EV-201, EV-203, EV-203TC, EV-300, EV-301, EV-303, EVM-100, EVM-110, EVM-200, EVM-210, FL100, FP01, FP-D71, FP-D74, FP-D75, FP-I71, FP-I74, FP-I75, FRD10, FRD20, FX-111, FX-112, FX-113, FX-211, FX-212, FX-213, FX-214, FX-215, GL-100, GL-101, GL-102, GL-103, GL-104, GL-105, GL-106, GL-107, GL-115D, GL-115I, GL-116, GL-117, GL-118, GL-121, GL-122,

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GL-123, GL-124, GL-200, GL-201, GL-202D, GL-202I, GL-203, GL-204, GL-205, GL-206, GL-207, GL-208, GL-300, GL-410, GL-420, H100, H101, H102, HO4001, HV-30, HV-31, HV-32, HV-33D, HV-33I, I-112, I-150, I-155, IC-30, IC-40, IH-112, IR-4000, IR-5000, IR-5001, IR-5002, IR-5100, IR-6000, IR-6001, IR-6002, IR-7000, IR-7001, IR-7002, J001, J001A, J002, J002A, J003, J003A, J004, J100, J101, KC101, KC200A, KC201, KITDS, KIT-LIMFLEX, L-250, LB2800, LB2801, LB3000, LB3001, LFT160, LFT340, LFT350, LFT351, LFT480, LFT490, LI1001, LI1002, LI1003, LI1004, LI1005, LSOA-B, LSO-B, LSOC-B, LT-280, LT-280R, LT-283, LT-284, LT-290, LT-294, LT-300, LT-300R, LT-303, LT-304, LT-310, LT-320, LT-320R, LT-330, LTB-280, LTB-284, LTB-304, LTG-105, LTG-275, LTG-285, LTG-305, LTG-375, LTN-284, LTN-304, M600, M660, M660P, M670, M670P, M700, M710D, M710I, M760, M770, MF-62, MF-62H, MF-62V, MF-D50, MF-D51, MF-D52, MF-D60, MF-D61, MF-I50, MF-I51, MF-I52, MF-I60, MF-I61, MFP-D80, MFP-D81, MFP-D90, MFP-D91, MFP-I80, MFP-I81, MFP-I90, MFP-I91, ML-240, MN3050, MO15, MO15AB, MO15ABF, MO15D, MO15F, MO15FD, MP-D70, MP-D72, MP-I70, MP-I72, NP-050, NP-051, NP-052, O-104, OCR100D, OCR100I, OCR200D, OCR200I, OCR204, OCR205E, OCR205F, OM001, OM6101D, OM6101I, OM6201, OP1130, OP1131, OP1132, OP1133, OP1140, OP1141, OP1150, OP1151, OP1152, OP1153, OP1154, OP1155, OP1156, OP1157D, OP1157I, OP1160, OP1161, OP1170, OP1172, OP1173, OP1174D, OP1174I, OP1172-FUND, OP1180, OP1181, OP1182, OP1183, OP1184, OP1190, OP1191, OP1192, OP1193, OP1194, OP1195D, OP1195I, OP1196D, OP1196I , OP1197D, OP1197I, OP1198D, OP1198I, OPH101, OS6110, OS6210, OS6211, OS6230, OS6240, OS6241, OS6260, OS6261, OS6706, OS6801, OS6804, OV01D500, OV02D500, OV02D501, OV03B005, OV04B000, PAD-TP2102, PANCP, PANW, PF009, PF010, PL-700F, PL-701F, PL-702, PL-705EF, PL-706EF, PL-750, PL-750F, PL-755, PL-755F, PL-760, PL-760F, PL-BION, PLA-BODYS, PM10, PS-17, PS-18, PS-19, PS-20, PS-21, PS-22, PS-23, PT-050, PT-050-P, PT-051, PT-051-P, PT-054, RR-ML-NEGRO, RR-NE-NEGRO, S-120, S-121, S-130, SD100, SD101, SD102, SD103, SD104, SD110, SD111, SD112, SD113, SD115, SP110, T-420, T-421, TACE01, TC101, TC200A, TC201, TL-601, TL-611, TL-612, TL-613, TL-614, TL-615, TL-616, TL-617-05, TL-617-10, TL-618F, TL-619, TL-620, TLSOA-B, TLSO-B, TN-210, TN-211, TN-230, TN-240, TN-241, TN-260, TN-261, TN-262, TOB-500B, TOB-500N, TP-2100, TP-2102D, TP-2102DM, TP-2102I, TP-2102IM, TP-4500, TP-4500C, TP-4800, TP-4801, TP-6100D, TP-6100I, TP-6101D, TP-6101DA, TP-6101I, TP-6101IA, TP-6102D, TP-6102I, TP-6103D, TP-6103I, TP-6104D, TP-6104I, TP-6105D, TP-6105I, TP-6200, TP-6300, TP-6301D, TP-6301I, TP-6400, TP-6401, TP-6402, TP-6500D, TP-6500I, TPA-2100.1

COMPROMISES TO: institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risk in relation to the product. Likewise,

COMPROMISES TO: notify the competent authorities of the following incidents immediately on learning of them:

a) Any malfunction or deterioration in the characteristics and/or the performance of a device, as well as any inadequacy in the labelling or the instructions for use which might led to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

b) Any technical or medical reason connected with the characteristics on the performance of the device for the reasons referred to in subparagraph (a) leading to systematic recall of devices of the same type by the manufacturer.

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