



CE DECLARATION OF CONFORMITY

NAME AND ADDRESS OF THE FIRM: İB-ER MAK. SAN. TİC.LTD. ŞTİ.
SELVİLİTEPE MAH. KEMALPAŞA SK.
NO:20/2 TURGUTLU- MANISA/ TURKEY

WE DECLARE UNDER OUR SOLE RESPONSIBILITY THAT:

EQUIPMENT:Carbon Foot & Foot Shell , Sach Foot and Adapters,Dynamic Foot and Adapters,Single Axis Foot and Adapters,Pyramid Receivers,Slide Adapter,Pyramid Adapters,Tube Assembly,Aluminum Tubes,Tube Clamp Adapters,Lamination Anchors,8 Screw Double Adapter,Attachment Blocks,Knee Joints,Silicone Liners & Locks System,Active Vacuum Unit&Valves,Foam Cover,Orthotic Components

ARTICLE NUMBER: E01s-M10, E01T-M10, E01s-M8, E01T-M8, E01AI-M10, E01AI-M8,E02s, E02T, E02AI, E02s-2, E02T-2, E02s-2D, E03s,E03s-ECC-A,E03s-ECC-D,E03T-ECC-A,E03T-ECC-D,E03T, E03AI, E03s-2, E03T-2,E03T-4,E03s-4 , E04T , E04s , E05T-10D-250,E05T-10D-400, E05T-20D-250,E05T-20D-400,E05s-10D-250, E05s-10D-400,E05s-20D-250,E05s-20D-400,E05s-400, E05s-250, E05T-400, E05T-250, E05AI-400, E05AI-250, E06s, E06T, E07s, E07s-10D, E07s-20D, E07T, E07T-10D, E07T-20D , E07AI,E09s-Body, E09s-Rs, E09s-RT, E09s-Ps, E09s-PT , E10s-Body, E10s-Rs, E10s-RT, E10s-Ps , E10s-PT,E09s-Rs-long,E09s-Ps-long, Rs-short, RT-short, Ps-short, PT-short,Rs-long,Ps-long,E09s-PT-long,E09s-RT-long,RT-long,PT-long,H03s, H03T, E11s, E12s, E12T-134, E12AI,E12TH,E12sH,E13s, E15s-32, E15s-45, E15s-60, E15s-75, E15T-32, E15T-45, E15T-60, E15T-75, E15AI-32, E15AI-45, E15AI-60, E15AI-75, E18s, E18T, E18AI, E19-75, E19-80, E19-85, E19-90 , E20 thin, E20 thick, E21s-32, E21s-34, E21s-45,E21s-60,E21s-75,E21T-32, E21T-34, E21T-45, E21T-60,E21T-75,E30s, E30T, E31s, E31T, E33T ,E33s,E34T, E34s,E40,E41, E41-Body,E41-adapter,E41-pyramid, E41-Prong Connection,E41-One Prong, E41-wire, E42s, E42T, E42-EXT, E43s, E43T E45s,E45T,E46s,E47,E48,E49AI, E50s(22-25),E50s(26-30) , E50T (22-25) , E50T(26-30),E50AL(22-25), E53s, E57s-32, E57T-32, E57s-60, E57T-60, E60, E61, E65,E66, E66c , E67,E67c,E68,E70-Body,E70-Kit,E71-Body,E71-Kit,E72, E90 sanis, E91-66,E91-78 , E91-88, E02s-134kg,E03s-134kg,E03s-4-134kg,E05s-250-134kg , E05s-400-134kg, E07s- 134kg,E09s-Body-134kg,E09s-Rs-134kg,E09s-Ps-134 kg,Ps-Short-134kg, Rs-Short-134kg ,E13s-134kg,E02T-134kg,E03T-134kg , E03T-4-134kg,E05T-250-134kg , E05T-400-134kg , E07T-134kg,AL350-100kg, AL400-100kg, AL450-100kg , AL500-100kg,AL350-134kg,AL400-134kg,AL450-134kg,AL500-134kg,E60-mika, AS-23-L,AS-23-R,AS-24-L,AS-24-R,AS-25-L,AS-25-R,AS-26-L,AS-26-R,AS-27-L,AS-27-R,AS-28-L,AS-28-R,AS-29-L,AS-29-R, FST,S-CF,E72-50,E72-36 ,Winged Carbon Foot,Short Carbon Foot,Supreme Carbon Foot,OAJ110, OKJ120, OLB110, OLB120, CLS110, OKJ110, OKJ120, OKJ130, OKJ140, VAC-100, VAC-200, VAC-300, VAC-400,E62,E61 cup,E04s-Rs,E04s-Ps,E04T-RT,E04T-PT,E06s-5mm,E06T-5mm,E09s-Large Body, E09s-Large Body-Ps, E09s-Large Body-Rs,Silicone Liners,E70-09 KIT,E71-09 KIT,E73-Disk,E73-Body,E73 KIT,Self-Fix,VAC-125-34,VAC-200-EXT,VAC-500,HJ-100,HJ-200

To which this declarations relates to are Class 1 according to Medical Directive 93/42/CE, Annex VII, amended by directive 2007/47/CE

THE ABOVE MENTIONED PRODUCTS ARE IN CONFORMITY WITH THE FOLLOWING STANDARDS:

- **ISO 10328** Structural testing of lower-limb prostheses
- **ISO 14971** Risk Analysis
- **Directive 93/42/CE, Annex VII, amended by directive 2007/47/CE**

Authorized Representative in EC

Ercan Gözüacık
Reinickendorfer Str 45
13347 Berlin
GERMANY

RESPONSIBLE OF THE COMPANY

Erol ERYILMAZ
General Manager
IB-ER MAK.SAN.TIC.LTD.STI.

This declaration is valid from JUNE 10,2014