



DECLARATION OF CONFORMITY

Manufacturer: Medex International, Inc.
2720 Duvall Rd
Burtonsville,
MD 20866
USA

SRN: Not available

EU Authorised Representative: Eurolink Europe Compliance Limited
25 Herbert Place
Dublin
D02 AY86
Republic of Ireland

SRN: Not available

We the undersigned certify and declare under our sole responsibility that the following apparatus

Conforming Apparatus: External Limb Prosthesis and Accessories - Prosthesis
Pyramids

Device Name: See page 2

Risk Class: MDR Annex VIII Rule 1

UDI-DI Number See pages 2 to 3

**Health Products Regulatory Authority
Registration Reference:** MDROEO202004021352 #3

Technical Document Reference No: TF0001-2A

Common Specifications EN 1041:2008 + A1:2013
EN 15223-1:2016
EN ISO 14971:2019
EN ISO 10328:2016

conforms to the requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL of 5 April 2017 on medical devices

Date: 1 February 2021

Signed:

D. R. M. Green - Authorised Representative

Issued: Dublin, Ireland

Product	Model Number	UDI-DI
SACH FOOT ADAPTER [8MM BOLT]	2T09	00810053310007
SACH FOOT ADAPTER [10MM BOLT]	2T10	00810053310014
SACH FOOT ADAPTER [ROUND, 10MM BOLT]	2T11	00810053310021
LONG TUBE WITH PYRAMID ADAPTER - 400 x 30 x 2.5MM	2T14	00810053310052
PYRAMID ADAPTER W/ 4 HOLES [10MM CENTER HOLE]	3T09	00810053310120
PYRAMID ADAPTER W/ 4 HOLES	3T10	00810053310137
PYRAMID ADAPTER W/ 4 HOLES [8.2MM CENTER HOLE]	3T10	00810053310144
PYRAMID ADAPTER W/ 4 HOLES [AXIAL OFFSET]	3T11	00810053310151
PYRAMID ADAPTER W/ 4 HOLES [DIAGONAL OFFSET]	3T12	00810053310168
PYRAMID ADAPTER W/ 4 PRONGS [HEAVY DUTY]	3T13	00810053310175
PYRAMID ADAPTER W/ 4 PRONGS	3T14	00810053310182
PYRAMID ADAPTER W/ 4 PRONGS - ROTATABLE	3T15	00810053310199
HEAVY DUTY PYRAMID ADAP. W/4 HOLES 8.2MM CENTER HOLE [THREADED ROTATION]	3T18	00810053310229
HEAVY DUTY PYRAMID ADAP. W/4 HOLES 10MM CENTER HOLE [THREADED ROTATION]	3T19	00810053310236
PYRAMID ADAPTER W/ 4 HOLES [THREADED ROTATION][DIAGONAL OFFSET]	3T24	00810053310267
PYRAMID ADAPTER W/ 4 HOLES [THREADED ROTATION][AXIAL OFFSET]	3T25	00810053310274
4 HOLE ROTATABLE PYRAMID W/ SLIDE	3T30	00810053310304
ARCH SLIDE ROTATABLE PYRAMID ADAPTER W/ 4 HOLES	3T31	00810053310311
4 SCREW AND PYRAMID DOUBLE HEAD ADAPTER	3T60	00810053310434
ROTATABLE MALE/FEMALE STAT ADAPTER 42MM	3T61	00810053310441
ROTATABLE MALE/FEMALE STAT ADAPTER 34MM	3T63	00810053310458
BOTH END PYRAMID ADAPTER [SHORT]	3T70	00810053310489
SLIDING ADAPTER - MALE-FEMALE	3T81	00810053310502
ROTATABLE/SLIDING PYRAMID/RECEIVER ADAPTER	3T83	00810053310526
SLIDING ADAPTER - MALE-TUBE CLAMP	3T86	00810053310540
ARCHED SLIDING TUBE CLAMP PYRAMID	3T88	00810053310564
TITANIUM 4 HOLE ROTATOR BASE	3T90	00810053310571
ARCHED SLIDING ROTATABLE PYRAMID/RECEIVER	3T96	00810053310595
ARCHED SLIDING PYRAMID/RECEIVER	3T99	00810053310618
PYRAMID INSERT	4T09	00810053310632
PYRAMID INSERT 2MM LONGER	4T10	00810053310649
PYRAMID INSERT 4MM LONGER	4T11	00810053310656
ROTATING/SLIDING PYRAMID INSERT	4T14	00810053310663
CLUTCH LOCK ROTATABLE 4 HOLE MOUNT W/ LAM. RIM	4T25	00810053310687
CLUTCH LOCK ROTATABLE 3 ARM	4T26	00810053310694
CLUTCH LOCK ROTATABLE 4 PRONG	4T28	00810053310700
3 ARM A/K ROTATABLE LAMINATION ANCHOR W/ SLIDING PYRAMID	4T41	00810053310724
ARCHED SLIDING PYRAMID INSERT	4T50	00810053310731
SACH FOOT ADAPTER	2S10	00810053310755
PYRAMID ADAPTER W 4 HOLES	3S10	00810053310809
PYRAMID ADAPTER W/ 4 HOLES, AXIAL OFFSET	3S11	00810053310816
PYRAMID ADAPTER W/ 4 HOLES, DIAGONAL OFFSET	3S12	00810053310823

PYRAMID ADAPTER W/ 4 PRONGS	3S14	00810053310830
ROTATING PYRAMID ADAPTER W/ 4 PRONGS	3S15	00810053310847
PYRAMID ADAP. W/ 4 HOLES [THREADED ROTATION]	3S18	00810053310861
4 SCREW AND PYRAMID DOUBLE HEAD ADAPTER	3S60	00810053310939
BOTH END PYRAMID ADAPTER [SHORT]	3S70	00810053310946
ROTATING PYRAMID ONLY	4S09	00810053310977
3 ARM A/K ROTATABLE LAMINATION ANCHOR [W/ TITANIUM PYRAMID]	4ST8	00810053311004
3 ARM A/K PYRAMID LAMINATION ANCHOR	4S20	00810053311011
3 ARM A/K ROTATABLE LAMINATION ANCHOR [W/ PYRAMID]	4S40	00810053311035
SACH FOOT ADAPTER	2A10	00810053311042
PYRAMID ADAPTER W/ 4 HOLES	3A10	00810053311110
PYRAMID ADAPTER W/ 4 PRONGS	3A14	00810053311127
PYRAMID ADAPTER W/CENTER HOLE [ROTATABLE]	3A18	00810053311134
4 SCREW AND PYRAMID DOUBLE HEAD ADAPTER	3A60	00810053311202
4 SCREW MOUNTING SHUTTLE LOCK W/ LAMINATION RIM	4A25	00810053311219
LARGE LAMINATION PLATE W/ PYRAMID	4TL1	00810053311240
MEDIUM LAMINATION PLATE W/ PYRAMID	4TM1	00810053311264
SMALL LAMINATION PLATE W/ PYRAMID	4TS1	00810053311288
SAFETY KNEE JOINT [TI]	5T40	00810053311301
SAFETY KNEE JOINT [TI] WITH LOCK AND INTERNAL EXTENSION ASSIST	5T50	00810053311318
CHILD SACH FOOT ADAPTER	2CT5	00810053311325
CHILD PYRAMID WITH 4 HOLES	3CT5	00810053311394
CHILD ROTATABLE PYRAMID WITH 4 HOLES	3TC1	00810053311448
CHILD DOUBLE HEAD ROTATABLE PYRAMID/ RECEIVER 26MM	4CT1	00810053311462
CHILD DOUBLE HEAD ROTATABLE PYRAMID/ RECEIVER 37MM	4CT2	00810053311479
CHILD DOUBLE HEAD ARCHED SLIDING PYRAMID/ RECEIVER	4CT8	00810053311493
CHILD LAMINATION 3 ARM ANCHOR WITH ROTATION PYRAMID	4TC2	00810053311523
CHILD LAMINATION 4 ARM ANCHOR WITH ROTATION PYRAMID	4TC4	00810053311547
CHILD LAMINATION RIM WITH ROTATING PYRAMID	4TC5	00810053311554