

## **EC DECLARATION OF CONFORMITY**

Manufacturer: 2S Paramedical Equipment  
Iroon Polytechniou 29  
13451 Kamatero, Athens  
Telephone No. 0030210232012-013

Product: Lower limb orthoses

We declare, that the above products, specified in the annexed product list **Product List E 07A-08EN**, to which this declaration relates, are in conformity with the provisions of Council Directive 93/42/EEC (14 June 1993) concerning medical devices, as amended by Council Directive 2007/47/EC (5 September 2007). Products belong to **Class I** as described in Annex IX.

The Technical File required by this Directive is maintained at the corporate headquarters of 2S Paramedical Equipment, Iroon Polytechniou 29, 13451 Kamatero, Athens, Greece.

2S PARAMEDICAL EQUIPMENT LTD.  
25 ΙΑΤΡΙΚΟΙ-ΠΑΡΑΙΑΤΡΙΚΟΙ ΕΞΟΠΛΙΣΜΟΙ ΕΠΕ  
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**General Manager**

Kamatero 23 March 2014

**Annexed: Product List E 07A-08EN**

E 07-08EN  
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Approved: Sotiropoulou

**2S Paramedical Equipment Ltd is certified to ISO 9001 Certificate No. 2013V852 and  
ISO 13485 Certificate No. 2013V852M**

## Product List

**Product:** Lower limb orthoses

i	Type	Description
1.	10.04.001	Thermal knee support
2.	10.04.002	Elastic knee support
3.	10.04.007	ROM Knee Brace
4.	10.04.008	Knee Immobilizer
5.	10.04.010	Neoprene knee support with flexible stays
6.	10.04.011	Elastic knee support with pad (closed patella)
7.	10.04.013	Neoprene Knee Support
8.	10.04.015	Wraparound Neoprene Hinged Knee Brace
9.	10.04.016	Patella Strap – one size
10.	10.04.017	Neoprene J-Shaped Knee Support with spiral stays
11.	10.04.020	Knee Brace with Four Point Hinge
12.	10.04.022	Neoprene Thigh Sleeve
13.	10.04.023	Neoprene shin sleeve
14.	10.04.024	Neoprene hip splint
15.	10.04.025	ROM hip Brace
16.	10.04.027	Elastic knee support with pad N
17.	10.04.028	Elastic knee support with pad and flexible stays (open patella) N
18.	10.04.029	Elastic knee support with silicone pad and flexible stays (closed patella) N
19.	10.04.030	Elastic knee support with pad and flexible stays (closed patella) N
20.	10.04.031	Patella and ligament knee support with flexible stays N.
21.	10.04.034	Hinged neoprene knee brace N.
22.	10.04.035	Elastic knee brace with hole
23.	10.04.037	Elastic knitted knee support
24.	10.05.001	Elastic Pull-Over ankle support
25.	10.05.002	Neoprene ankle brace with straps
26.	10.05.004	Elastic ankle support with pad
27.	10.05.005	AirCast – one size
28.	10.05.006	Ankle Foot Orthosis (AFO)
29.	10.05.007	Night / Resting AFO
30.	10.05.008	Hallux Valgus (bunion) day strap– one size
31.	10.05.009	Hallux Valgus padded support night– one size
32.	10.05.013	Elastic Pull-Over ankle support with open heel
33.	10.05.014	Neoprene ankle brace with rigid inserts
34.	10.05.015	Functional ankle splint
35.	10.05.016	Functional ankle brace (cletzak)
36.	10.05.018	Ankle brace
37.	10.05.019	Achilles tendon ankle support
38.	10.05.020	Lace Up ankle support brace
39.	10.05.023	Elastic knitted ankle support
40.	10.07.008	Wraparound neoprene knee support – one size
41.	10.07.009	Wraparound neoprene knee support with flexible stays– one size
42.	10.07.010	Neoprene figure 8 ankle support– one size

43.	10.09.003	Kids; open heel figure 8 ankle support
44.	10.09.004	Kids' ankle support with pad
45.	10.09.014	Kids' neoprene ankle support
46.	10.09.015	Kids' neoprene knee support with flexible stays
47.	10.09.022	Kid's Night / Resting ankle foot orthosis
48.	10.09.023	Pavlik harness
49.	10.09.024	Frejka pillow splint
50.	13.00.001	Silicone toe separators
51.	13.00.002	Metatarsal cushion – one size
52.	13.00.003	Orthopedic insole
53.	13.00.004	Silicone Insoles
54.	13.00.005	Silicone Insoles ¾
55.	13.00.006	Silicone heel cushions
56.	13.00.008	Silicone metatarsal pad
57.	13.00.009	Silicone arch supports
58.	13.00.010	Silicone insoles for calcaneal valgus and calcaneal varus feet
59.	13.00.012	Plaster cast supporting full sole
60.	13.00.015	Plaster cast supporting heel large
61.	13.00.016	Metatarsal pad double stars
62.	13.00.017	Silicone heel cushions double stars
63.	13.00.018	Leather cork insoles
64.	13.00.019	Leather insoles ¾
65.	13.00.020	Silicon insoles with ring double stars
66.	13.00.021	Silicone toe tube double star
67.	13.00.022	Silicone toe separator double stars
68.	13.00.024	Silicon insole with pad mtt double stars