



Next-Generation Limb Support

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Medical Device EC DECLARATION OF CONFORMITY

Manufacturer: Orthoflex Ltd., 12 Lincoln St., Haifa 3436914, Israel.
Tel: +97248388778, Fax +97248244558.

Products: **Inflatable Splints**

Placed the products in the European market, declare that our products conform and meet the essential requirements set out in Annex I of the Medical Device Directive 93/42 EEC & MDD2007/47.

The device was registered in MHRA – the UK competent Authority registration #
CA 008554

Product:

Inflatable splints

Class:

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Conforming to Production Standards:

- ❖ MDD 93/42EEC & MDD 2007/47 EEC
- ❖ Statutory Instrument 2002 No. 618 The Medical Devices Regulations 2002

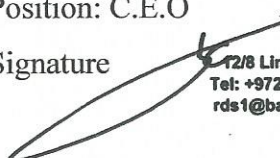
Appointed EU Authorized Representative: Within those requirements we prepared the required technical documentation, put into place corrective action and vigilance procedures and have appointed Medes Limited, 5 Beaumont Gate, Shenley Hill, Radlett, Herts WD7 7AR. England Tel: +423-663-169205 Tel / Fax: +44 1923859810 , to act as our Authorized Representative in the European Community.

Full Name: Arye Oko

Date: 09/ 21/ 2014

Position: C.E.O

Signature


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