

EC Declaration of Conformity

Legal Manufacturer: BeneCare Medical (a trading name of Benefoot (UK) Ltd)

Branson Court, Branson Street, Manchester, M40 7FP,

United Kingdom.

Name of Device Ranges: Bandages, Splints/Collars, Orthopaedic Footwear, Orthoses,

Orthopaedic Casting Materials, Supports and Bracing, Low

Temperature Thermoplastics and accessories.

Classification (MDD, Annex IX): Class I

I the undersigned, herewith declare that the above mentioned product(s) meet the provisions of the following EC Council Directives and harmonised standards. All supporting documentations are retained under the premise of the legal manufacturer and the notified body.

DIRECTIVES

General applicable directives: EC DIRECTIVE: Medical Devices Directive -

(MDD 93/42/EEC amended by 2007/47/EC)

Conformity assessment route: Conformity assessment was performed according to

Article II (5), Annex VII Section 3.

Standard used: EN ISO 13485

Notified body: MHRA Regulatory Agency (Ref no. CA012187)

151 Buckingham Palace Road, Victoria, London, SW1W 9SZ

Place: BeneCare Medical; UK Date: September 1, 2012 Signature:_ Name:

Name: Ian Lachs Position: Managing Director

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