

EC Declaration of Conformity

Manufacturer :

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Declares that the product,

Trade/proprietary name : Curble Chair

Model Name : Comfy_black, Comfy_blue, Comfy_g, Comfy_r, Wider_b, Wider_g, Wider_r,
KIDS I MINT, KIDS I PINK, KIDS I BLACK

GMDN Code : 33031

GMDN Term : Orthosis, Lumbar spine

Classification : Class I (Rule 1)

Applied Standards : MEDDEV 2.4.1 Rev.9

MEDDEV 2.7.1 Rev.4

MEDDEV 2.12.1 rev.8

MEDDEV 2.12.2 rev.2

EN ISO 13485:2016

EN ISO 14971:2012

ISO15223-1:2016

ISO 14155:2011, ISO 15223-1:2016

EN 1041:2013, EN 62366:2008, EN 62304:2015

93/42/EEC as amended by Directive 2007/47/EC

Definition : An externally applied orthopaedic appliance or apparatus that encompasses the lumbar spine region of the trunk and is used to support or immobilize deformities, fractures, sprains, or strains of the spine.

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC for medical devices.

All supporting documentation is retained under the premises of the manufacturer.

“The manufacturer is exclusively responsible for the declaration of conformity”

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