Klarity

www.klaritymedical.com

EC DECLARATION OF CONFORMITY

According to annex VII of the Council Directive 93/42/EEC (Amended by 2007/47/EC) concerning medical devices,

We,

Klarity Medical & Equipment (GZ) Co., Ltd.
Floor 1-6, No.14, 3rd Street Shawan, GETDD
Guangzhou, Guangdong, China

declare under our sole responsibility that the following non-sterile products under Class I meet the provisions of the Council Directive 93/42/EEC(Amended by 2007/47/EC) concerning medical devices which apply to them:

Thermoplastic Mask for Radiation therapy, Patient Positioning System (Carbon Fiber Boards, Tables and Support Devices, Vacuum Cushions, Positioning Pads, Kneefix), Mold Cushions (AccuCushions)

These products are intended to be used for positioning a patient during Radiation Therapy treatments, and medical use as splints, braces and limb orthoses that are worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement.
Conformity assessment was performed according to Annex VII.

The products concerned were manufactured under the following quality management system established:

EN ISO 9001:2015	Certificate No.: 20832
EN ISO 13485:2016	Certificate No.: IT275797

European Authorized Representative,

Lotus Global Co., Ltd.

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