A Higher Standard for Thermoplastics

Klarity

80 Westgate Dricve
Newark, Ohio 43055 USA
www.klaritymedical.com
740.778.8107 phone
740.788.8109 fax
email info@klaritymedical.com

KLARITY MEDICAL PRODUCTS

EC DECLARATION OF CONFORMITY

According to annex VII of the Council Directive 93/42/EEC (amended2007/47/EC) concerning medical devices:

We: Klarity Medical Products
80 Westgate Drive
Newark, OH 43055 USA

Declare that the following non-sterile medical devices under class I (according to rule 1 of annex IX of the Council Directive 93/42/EEC):

KLARITY Carbon Fibre Devices for Radiation Therapy Patient Stabilization

R601 Head Baseplate	R606 HipLok™ Baseplate
R602 Tilting Head Baseplate	R610 Breast Board
R604 Head&Neck Baseplate	R620-A Pelvis/Belly Board
R605 AIO Baseplate	R620-B Prone Breast System

fulfill the basic requirements according to annex I no. 1-14 of the Council Directive 93/42/EEC (amended 2007/47/EC)

Conformity assessment was performed according to Annex VII.

The above products were manufactured under the following quality management systems:

EN ISO 9001:2000 Certificate No.: 20832
EN ISO 13485:2003 Certificate No.: Q2N 11 11 49007 004

Peter M. Larson
President
Klarity Medical Products
Newark, Ohio USA
December 14, 2010

Authorized European Representative:
Lotus Global Co., Ltd.
18 Alexandra Road
London, UK NW8 0DP
Ph. +44 20 7586 8010
Fax: +44 20 7900 6187