Better Products for Better Care

Klarity Medical Products, LLC
600 Industrial Parkway
Heath, Ohio 43056 USA
www.klaritymedical.com
740.788.8107 ph.
740.788.8109 fax
Email: info@klaritymedical.com

DECLARATION OF CONFORMITY

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

We: Klarity Medical Products LLC
600 Industrial Parkway
Heath, OH 43056 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® Brand thermoplastic masks, vacuum bags, cushions, acrylic and carbon fiber boards, table and accessories for stabilization of patients for external beam radiation therapy

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.

These products are registered with the United States Food and Drug Administration and conform to all FDA quality and production requirements.

These products are further guaranteed to perform their intended functions and are compatible with international standard treatment tables and boards as manufactured by Siemens, Elekta, Varian, Civco, Qfix and other manufacturers.

Affirmed June 21, 2022

Peter M. Larson
President
Klarity Medical Products LLC
Heath, Ohio USA

Authorized European Representative:
AJW Technology Consulting GmbH
Königsallee 106
40215 Düsseldorf (Germany)