

DECLARATION OF CONFORMITY

According to Regulation (EU) MDR 2017/745 of the European Parliament 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 EU MDR 2017/745):

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 EU MDR 2017/745.

Conformity assessment was performed according to Article 52.

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.

The above products are manufactured under the following standards:

EN ISO 9001:2015
EN ISO 13485:2016

Affirmed February 13, 2024



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



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