Better Products for Better Care

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DECLARATION OF CONFORMITY

According to annex IV of the EU MDR 2017/745 (amended2001/83/EC) concerning medical devices:

We: Klarity Medical Products LLC
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declare that the following non-sterile medical devices under class I (according to Article 19 of annex IV of the EU MDR 2017/745):

KLARITY® Brand thermoplastic masks, vacuum bags, vacuum pump, 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 IV no. 1-10 of the EU MDR 2017/745 (amended 2001/83/EC). Conformity assessment was performed according to Annex IV.

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

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

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

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 15, 2023

Peter M. Larson
President
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