Better Products for Better Care

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DECLARATION OF CONFORMITY

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

KLARITY® AccuCushions™ moldable cushions for patient positioning.
KLARITY® BiteLok™ teeth and jaw positioning device

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 were manufactured under the following quality management systems:

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
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