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Better Products for Better Care

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

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 February 19, 2021

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

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