

KLARITY MEDICAL PRODUCTS

EC DECLARATION OF CONFORMITY

According to annex VII of the Council Directive 93/42/EEC (amended 2007/47/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 items for medical splints, casts and 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.

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

EN ISO 9001:2000 Certificate No.: 20832

EN ISO 13485:2003 Certificate No.: Q2N 11 11 49007 004



Peter M. Larson
President
Klarity Medical Products LLC
Heath, Ohio USA
February 19, 2021

Authorized European Representative:
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