A Higher Standard for Thermoplastics

600 Industrial Parkway
Heath, Ohio 43056 USA
www.klaritymedical.com
740.778.8107 phone
740.788.8109 fax
email info@klaritymedical.com

KLARITY MEDICAL PRODUCTS

EC 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 items for medical splints, casts and 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.

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

EN ISO 9001:2015 Certificate No.: C2023-00423-T
EN ISO 13485:2016 Certificate No.: IT324899-1

Peter M. Larson
President
Klarity Medical Products LLC
Heath, Ohio USA
February 02, 2024

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