

# EU MDR Compliance Statement

European Union Medical Device Regulation (2017/745), also known as EU MDR, went into effect in 2021. It places restrictions and reporting requirements on substances used in the design and manufacturing of medical devices.

Volara®, Volextra® and VolaraBLOCK® are not medical devices, thus are not obligated to report or meet the restrictions set by EU MDR. Nonetheless, all chemicals used in the manufacturing of Volara®, Volextra® and VolaraBLOCK® are excluded from the EU MDR list, or are under the 0.1% concentration limit.

## MARKETING BULLETIN

December 2023

Because we cannot anticipate or control the many different conditions under which this information and our products may be used, we do not guarantee the applicability of the accuracy of this information or the suitability of our products in any given situation. Users of our products should make their own tests to determine the suitability of each product for their particular purposes. The products discussed are sold without warranty, either expressed or implied, and buyer assumes all responsibility for loss or damage arising from the handling and use of our products, whether done in accordance with directions or not. Also, statements concerning the possible use of our products are not intended as recommendations to use our products in the infringement of any patent.