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.

17 Allen Ave, Coldwater, MI 49036 Tel: (833) 517-1627 Fax: (517) 279-8562
www.sekisuivoltek.com Email: Prodinfo@sekisuivoltek.com

SEKISUI | VOLTEK