

CERTIFICATE

Number: 3823106

The management system of:

Trelleborg Sealing Solutions US, Inc.

2761 Walnut Ave
Tustin, CA 92780
United States Of America

including the implementation meets the requirements of the standard:

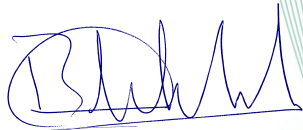
ISO 13485:2016

Scope:

Contract manufacturing of custom medical devices and combination drug/device products including long term implantables; including process development, assembly, sealing, packaging and sterilization management; utilizing bonding, over-coating with cross-linked porcine gelatin, drug mixing and coating technologies, and dry heat sterilization; intended for ophthalmology, general and plastic surgery, neurology, gynecology, urology, ENT (ear, nose and throat), anesthesiology, cardiology, general hospital and personal use.

Certificate expiry date: 9 September 2024
Certificate effective date: 9 September 2021
Certified since: 9 September 1997

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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