

CERTIFICATE

Number: 3807292

The management system of:

Avalon Laboratories, LLC

7612 Woodwind Dr.
Huntington Beach, CA 92647
USA

including the implementation meets the requirements of the standard:

ISO 13485:2003

Scope:

Contract manufacturing and development of medical products with contract engineering services supporting customer design and process development. Contract manufacturing processes include polymer solution casting, assembly, kitting, and packaging operations for catheters, cannulae, and tubing for applications such as cardiovascular, cardiopulmonary, peripheral access, neurovascular and gastrointestinal access. Additional processes include ultrasonic welding, injection molding, assembly and packaging for fluid management fittings, connectors, applicators and regulators used in the delivery of bone-graft and other biomaterials.

This certification also includes the location as identified on the addendum belonging to this certificate.

Certificate expiry date: 1 March 2019
Certificate effective date: 13 June 2017
Certified since: 15 September 2011

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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ADDENDUM 1/1

to Certificate 3807292

concerning the Management System of:

Avalon Laboratories, LLC

List of certified locations

Location	Certification scope
Avalon Laboratories, LLC Carretera Internacional KM129, Salida Norte, Sin Numero Parque Industrial Roca, Fuerte Guaymas, Sonora Mexico C.P. 85400	Contract manufacturing and development of medical products with contract engineering services supporting customer design and process development. Contract manufacturing processes include polymer solution casting, assembly, kitting, and packaging operations for catheters, cannulae, and tubing for applications such as cardiovascular, cardiopulmonary, peripheral access, neurovascular and gastrointestinal access. Additional processes include ultrasonic welding, injection molding, assembly and packaging for fluid management fittings, connectors, applicators and regulators used in the delivery of bone-graft and other biomaterials.

Addendum Initial date: September 15, 2011

Addendum Effective date: June 13, 2017

DEKRA Certification B.V.

Managing Director

Certification Manager

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