

Quality Management System Certification

Compliance

Location	Location Primary Functions	Certifications
Quidel Corporation 9975 Summers Ridge Road San Diego, CA 92121 USA	<ul style="list-style-type: none"> • Corporate Office / Executive Management • Administrative Support, Legal, Human Resources, Finance, Accounting, IS • Regulatory, Clinical • Sales, Marketing, Customer and Technical Support 	<ul style="list-style-type: none"> • ISO 13485:2016 • MDSAP
Quidel Corporation 9985 Summers Ridge Road San Diego, CA 92121 USA	<ul style="list-style-type: none"> • Research and Development 	<ul style="list-style-type: none"> • ISO 13485:2016 • MDSAP
Quidel Corporation 9965 Summers Ridge Road San Diego, CA 92121 USA	<ul style="list-style-type: none"> • Research and Development • Quality Assurance 	<ul style="list-style-type: none"> • ISO 13485:2016 • MDSAP
Quidel Corporation 10165 McKellar Court San Diego, CA 92121 USA	<ul style="list-style-type: none"> • Research and Development • Manufacturing • Manufacturing Support (Facilities, Engineering, Human Resources) • Quality Control <p>(Legal Manufacturer)</p>	<ul style="list-style-type: none"> • ISO 13485:2016 • MDSAP • IVDD
Quidel Corporation 10015 Waples Court San Diego, CA 92121 USA	<ul style="list-style-type: none"> • Distribution • Warehouse • Inspection • Purchasing 	<ul style="list-style-type: none"> • ISO 13485:2016 • MDSAP
Quidel Cardiovascular Inc. 9975 Summers Ridge Road San Diego, CA 92121 USA	<ul style="list-style-type: none"> • Manufacturing Support (Facilities, Engineering) • Human Resources • Metrology <p>(Legal Manufacturer)</p>	<ul style="list-style-type: none"> • ISO 13485:2016 • MDSAP
Quidel Cardiovascular Inc. 9985 Summers Ridge Road San Diego, CA 92121 USA	<ul style="list-style-type: none"> • Manufacturing • Manufacturing Support (Facilities, Engineering) • Quality Control 	<ul style="list-style-type: none"> • ISO 13485:2016 • MDSAP
Quidel Cardiovascular Inc. 9965 Summers Ridge Road San Diego, CA 92121 USA	<ul style="list-style-type: none"> • Manufacturing • Purchasing • Warehouse • Receiving Inspection • Quality Assurance 	<ul style="list-style-type: none"> • ISO 13485:2016 • MDSAP

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<p>Diagnostic Hybrids, Inc. 2005 E. State Street, Suite 100 Athens, OH 45701 USA</p>	<ul style="list-style-type: none"> • Manufacturing • Manufacturing Support (Facilities, Engineering) • Legal, Human Resources, Finance, Accounting, IS • Distribution • Regulatory, Clinical • Quality Control • Quality Assurance • Customer and Technical Support • Research and Development <p>(Legal Manufacturer)</p>	<ul style="list-style-type: none"> • ISO 13485:2016 • MDSAP • IVDD
<p>BioHelix Corporation 500 Cummings Ctr., Suite 5550 Beverly, MA 01915 USA</p>	<ul style="list-style-type: none"> • Research and Development • Manufacturing • Manufacturing Support • Quality Control • Quality Assurance <p>(Legal Manufacturer)</p>	<ul style="list-style-type: none"> • ISO 13485:2016 • MDSAP
<p>Quidel Ireland Ltd. Second Floor, Merchants Square Merchants Road Galway, Ireland H91 Y184</p>	<ul style="list-style-type: none"> • Europe, Middle East, Africa Sales, Marketing • Legal, Finance, Accounting, IS • Customer and Technical Support • Manufacturing • Distribution <p>(Legal Manufacturer)</p>	<ul style="list-style-type: none"> • ISO 13485:2016
<p>Quidel Italy S.r.l. Viale Donato Giannotti, 24 50126 Firenze FI Italy</p>	<ul style="list-style-type: none"> • Customer Service • Sales (Italy Only) 	<ul style="list-style-type: none"> • ISO 13485:2016 • ISO 9001:2015
<p>Quidel Germany GmbH Leibnizstr 11 70806 Kornwestheim Stuttgart, Germany</p> <p>(Legal Manufacturer)</p>	<ul style="list-style-type: none"> • Research and Development • Manufacturing • Quality Control • Quality Assurance 	<ul style="list-style-type: none"> • ISO 13485:2016
<p>Quidel China Ltd. Pudong - 315, 3-F, Building 1, 88 Sheng Rong Road,</p>	<ul style="list-style-type: none"> • Corporate Office (Legal) 	<ul style="list-style-type: none"> • Not Required / Not Applicable

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Pudong New District, Shanghai, PRC		
Quidel China Ltd. 30-06, 18th Floor, Office Tower 1, Raffles City, 1133 Changning Road, Changning District, Shanghai, PRC	<ul style="list-style-type: none">• Sales, Marketing (China Only)• Legal, Finance, Accounting, IS• Distribution• Customer and Technical Support• Regulatory (China Only)	<ul style="list-style-type: none">• Planned ISO 13485:2016
Quidel Canada Ltd.	<ul style="list-style-type: none">• Corporate Office (Legal)	<ul style="list-style-type: none">• Not Required / QMS Covered through Quidel Corporation
Quidel India	<ul style="list-style-type: none">• Corporate Office (Legal)	<ul style="list-style-type: none">• Not Required / QMS Covered through Quidel Corporation

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Agencies that are participating in the MDSAP include:

- Therapeutic Goods Administration of Australia
- Brazil's Agência Nacional de Vigilância Sanitária
- Health Canada
- Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency
- U.S. Food and Drug Administration

MDSAP Official Observers:

- The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme
- European Union (EU)
- MDSAP Affiliate Members: (New)
- Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT)
- Republic of Korea's Ministry of Food and Drug Safety

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