

Accreditation

by the ANSI-ASQ National Accreditation Board is hereby granted to

American Systems Registrar (ASR)

5281 Clyde Park Avenue SW, Suite 1
Wyoming, Michigan 49509 United States

as a certification body conforming to ISO/IEC 17021-1:2015 (with Option A as the management system) as of 30 June 2016, for providing audits and certifications of management systems in accordance with the standards listed below. The AQMS accreditation is based on AS9104/1:2012 as of 14 November 2012.

Standard	Accredited	Expiration
ISO 13485	27 April 2010	01 September 2022
ISO 14001	01 March 2001	01 September 2022
ISO 9001	01 September 1998	01 September 2022
AS9100	06 March 2009	01 September 2022
AS9120	10 April 2013	01 September 2022

Use of the IAF MLA Mark approved as of 20 July 2007

Scope of organization's products, processes, and services for which the certification body is authorized to issue ANAB ISO 13485 accredited Certifications:

- 1.1 Non-active Medical Devices: Devices for wound care
- 1.1 Non-active Medical Devices: General non-active, non-implantable medical devices
- 1.1 Non-active Medical Devices: Non-active dental devices and accessories
- 1.1 Non-active Medical Devices: Non-active implants
- 1.2 Active Medical Devices (Non-implantable): Devices for imaging
- 1.2 Active Medical Devices (Non-implantable): Devices for radiation therapy and thermo therapy
- 1.2 Active Medical Devices (Non-implantable): General active medical devices
- 1.2 Active Medical Devices (Non-implantable): Monitoring devices
- 1.2 Active Medical Devices (Non-implantable): Other
- 1.4 In Vitro Diagnostic Medical Devices (IVD): Reagents & reagent products, calibrators & control materials (see IAF MD 8)
- 1.5 Sterilization Method for Medical Devices: Moist heat

ANAB Accreditation, continued

American Systems Registrar (ASR)

Scope of organization's products, processes, and services for which the certification body is authorized to issue ANAB ISO 14001 accredited Certifications:

- 01 Agriculture, forestry and fishing
- 02 Mining and quarrying
- 03 Food products, beverages and tobacco
- 04 Textiles and textile products
- 05 Leather and leather products
- 06 Wood and wood products
- 07 Pulp, paper and paper products
- 08 Publishing companies
- 09 Printing companies
- 10 Manufacture of coke and refined petroleum products
- 12 Chemicals, chemical products and fibers
- 13 Pharmaceuticals
- 14 Rubber and plastic products
- 15 Non-metallic mineral products
- 16 Concrete, cement, lime, plaster, etc
- 17 Basic metals and fabricated metal products
- 18 Machinery and equipment
- 19 Electrical and optical equipment
- 20 Shipbuilding
- 21 Aerospace
- 22 Other transport equipment
- 23 Manufacturing not elsewhere classified
- 24 Recycling
- 25 Electricity supply
- 26 Gas supply
- 27 Water supply
- 28 Construction
- 29 Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods
- 30 Hotels and restaurants
- 31 Transport, storage and communication
- 32 Financial intermediation; real estate; renting
- 33 Information technology
- 34 Engineering services
- 35 Other services
- 36 Public administration
- 37 Education
- 38 Health and social work
- 39 Other social services

Scope of organization's products, processes, and services for which the certification body is authorized to issue ANAB ISO 9001 accredited Certifications:

- 01 Agriculture, Hunting, Forestry & Fishing
- 02 Mining and Quarrying
- 03 Food Products, Beverages and Tobacco
- 04 Textiles and Textile Products
- 05 Leather and Leather Products

ANAB Accreditation, continued

American Systems Registrar (ASR)

06	Wood and Wood Products
07	Pulp, Paper and Paper Products
08	Publishing Companies
09	Printing Companies
12	Chemicals, Chemical Products and Fibres
13	Pharmaceuticals
14	Rubber and Plastic Products
15	Non-metallic Mineral Products
16	Concrete, Cement, Lime, Plaster, etc.
17	Basic Metals and Fabricated Metal Products
18	Machinery and Equipment
19	Electrical and Optical Equipment
21	Aerospace
22	Other Transport Equipment
23	Manufacturing Not Elsewhere Classified
24	Recycling
25	Electricity Supply
29	Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods
30	Hotels and Restaurants
31	Transport, Storage and Communications
32	Financial Intermediation, Real Estate, Renting
33	Information Technology
34	Engineering Services
35	Other Services
36	Public Administration
37	Education
38	Health and Social Work
39	Other Social Services

Scopes are broad classifications which may include business activities for which a certification body's competence has not been demonstrated. The certification body is expected to make this clear to its own personnel and to potential customers, and to accept applications for certification only for those activities for which the certification body has the competence.

Countries in which the certification body has issued ANAB accredited certificates

Angola	Australia	Canada
Costa Rica	Egypt	El Salvador
France	Greece	Honduras
India	Kazakhstan	Korea, Republic of
Kuwait	Malaysia	Mexico
Nigeria	Puerto Rico	Saudi Arabia
Singapore	South Africa	Taiwan, Republic of China
Thailand	Turkey	United Arab Emirates
United States	Viet Nam	

ANAB Accreditation, continued

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Additional office locations. Critical locations are identified by an asterisk

1 Al Haram Mountasr Bldg, App #2, Al Talbia, Al Haram, Giza Egypt
657, Sector 15, Part-I, Gurgaon, Haryana India
#409, SM Plaza, 13, Chungseon-ro 209 beon-gil, Bupyeong-gu, Inchen Korea, Republic Of
Rm. 607, 6F., No.299, Sec. 4, Zhongxiao E. Rd., Da-an Dist, Taipei Taiwan, Republic Of China
5F., No. 384, Wenheng Rd., Fengshan Dist., Kaohsiung City Taiwan, Republic Of China
5F, No.109, Jianguo 1st Rd., Lingya District, Kaohsiung City Taiwan, Republic Of China
Hurriyet Bulvari No: 4/1, K:2 D:203 Kavala Plaza, Cankaya, Izmir Turkey

Signed for ANSI-ASQ National Accreditation Board

Lori Gillespie, Vice President, Management Systems

Certificate Number: ASR-1301617-180817

Certificate Issue date: 18 August 2017