

Schedule of Accreditation



Organisation Name	Business Quality Assurance International Ltd.
Trading As	BQAI
INAB Reg No	5007
Contact Name	Declan O'Connor
Address	Clarinbridge, Galway
Contact Phone No	+353 91 796017
Email	info@bqai.ie
Website	
Accreditation Standard	ISO 17021-1
Date of award of accreditation	30/01/2008
Scope Classification	27001
Scope Classification	IAF
Scope Classification	IAF MD8
Services available to the public ¹	Yes

¹ Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	Address
1	Head Office	Woodvale House, Clarinbridge, Galway

Scope of Accreditation

Head Office

ISO 27001

Standard -	Detail	Further Information				
ISO 27001:2017	Certification of Information Security Management Systems	Full				
<i>Assessed in conjunction with ISO/IEC 27006:2015 AMD1:2020</i>						

Head Office

ISO 9001

Code	NACE code	Detail
3	10.31	Processing and preserving of potatoes
3	10.39	Other processing and preserving of fruit and vegetables
3	10.85	Manufacture of prepared meals and dishes
3	10.91	Manufacture of prepared feeds for farm animals
6	16.23	Manufacture of other builders' carpentry and joinery
6	16.29	Manufacture of other products of wood; manufacture of articles of cork, straw and plaiting materials
9	18.12	Printing and service activities related to printing - other printing
12	20.13	Manufacture of other inorganic basic chemicals

12	20.14	Manufacture of other organic basic chemicals
14	22.19	Manufacture of other rubber products
14	22.22	Manufacture of plastic packing goods
12	22.29	Manufacture of other plastic products
23	32.99	Other manufacturing n.e.c
22	33.19	Repair of other equipment
17	24.41	Precious metals production
17	24.33	Cold forming or folding
17	25.11	Manufacture of metal structures and parts of structures
17	25.29	Manufacture of tanks, reservoirs and containers of metal
17	25.5	Forging, pressing, stamping and roll forming of metal; powder metallurgy
17	25.91	Manufacture of steel drums and similar containers
17	33.11	Repair of fabricated metal products
18	33.2	Installation of communications equipment
17	25.73	Manufacture of tools
17	28.4	Manufacture of metal forming machinery and machine tools
18	28.94	Manufacture of machinery for textile, apparel and leather production
18	28.96	Manufacture of plastic and rubber machinery
18	28.99	Manufacture of other special purpose machinery n.e.c
18	33.12	Repair of machinery
18	33.2	Installation of industrial machinery and equipment
19	26.2	Manufacture of computers and peripheral equipment
22	29.2	Manufacture of bodies (coachwork) for motor vehicles; manufacture of trailers and semi-trailers
24	38.11	Collection of non-hazardous waste
24	38.21	Treatment and disposal of non-hazardous waste
24	38.32	Recovery of sorted materials
24	39	Remediation activities and other waste management services
28	43.1	Demolition and site preparation
28	43.21	Electrical installation

28	43.29	Other construction installation
28	43.39	Other building completion and finishing
28	43.99	Other specialized construction activities n.e.c
29	45, 46, 47	Wholesale and retail trade; repair of motor vehicles and motorcycles
31	49.41	Freight transport by road
31	49.42	Removal services
31	52.1	Warehousing and storage
31	52.21	Service activities incidental to land transportation
31	79	Travel agencies, tour operators and other reservation service and related activities
32	65.1, 65.2	Insurance and reinsurance
33	62	Computer programming, consultancy and related activities
33	63	Information service activities
34	71.1	Architectural and engineering activities and related technical consultancy
34	74.2	Photographic activities
34	74.9	Other professional, scientific and technical activities n.e.c.
35	63.99	Other information service activities n.e.c.
35	69.1	Legal activities
35	70.21	Public relation and communication activities
35	70.22	Business and other management consultancy activities
35	74.1	Specialised design activities
35	78	Employment activities
35	81.2	Cleaning activities
35	82.2	Activities call centres
35	82.92	Packaging activities
35	82.99	Other business support service activities n.e.c
35	85.6	Educational support activities
37	Full	Education
38	86, 88.90	Human health activities/other social work activities without accommodation

Head Office

ISO 13485

Main Technical Areas (as per IAF MD8)	Technical Areas (as per IAF MD8)	Product Categories covered by the Technical Areas
Non-active medical devices	General non-active, non-implantable medical devices	Non-active medical devices other than specified above (moulded plastic parts)
Sales and distribution of non-active medical devices	General non-active, non-implantable medical devices	Non-active devices for anaesthesia, emergency and intensive care
Sales and distribution of non-active medical devices	General non-active, non-implantable medical devices	Non-active devices for injection, infusion, transfusion and dialysis
Sales and distribution of non-active medical devices	General non-active, non-implantable medical devices	Non-active orthopaedic and rehabilitation devices
Sales and distribution of non-active medical devices	General non-active, non-implantable medical devices	Non-active medical devices with measuring function
Sales and distribution of non-active medical devices	General non-active, non-implantable medical devices	Non-active ophthalmologic devices
Sales and distribution of non-active medical devices	General non-active, non-implantable medical devices	Non-active instruments
Sales and distribution of non-active medical devices	General non-active, non-implantable medical devices	Contraceptive medical devices
Sales and distribution of non-active medical devices	General non-active, non-implantable medical devices	Non-active medical devices for disinfecting, cleaning and rinsing
Sales and distribution of non-active medical devices	General non-active, non-implantable medical devices	Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
Sales and distribution of non-active medical devices	General non-active, non-implantable medical devices	Non-active medical devices for ingestion
Sales and distribution of non-active medical devices	Non-active implants	Non-active cardiovascular implants
Sales and distribution of non-active medical devices	Non-active implants	Non-active orthopaedic implants
Sales and distribution of non-active medical devices	Non-active implants	Non-active functional implants
Sales and distribution of non-active medical devices	Non-active implants	Non-active soft tissue implants
Sales and distribution of non-active medical devices	Devices for wound care	Bandages and wound dressings
Sales and distribution of non-active medical devices	Devices for wound care	Suture material and clamps
Sales and distribution of non-active medical devices	Devices for wound care	Other medical devices for wound care
Sales and distribution of active medical devices (non-implantable)	General active medical devices	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation

		anaesthesia.
Assembly of procedure packs containing non-active medical devices	General non-active, non-implantable medical devices	Non-active devices for anaesthesia, emergency and intensive care
Assembly of procedure packs containing non-active medical devices	General non-active, non-implantable medical devices	Non-active devices for injection, infusion, transfusion and dialysis
Assembly of procedure packs containing non-active medical devices	General non-active, non-implantable medical devices	Non-active orthopaedic and rehabilitation devices
Assembly of procedure packs containing non-active medical devices	General non-active, non-implantable medical devices	Non-active medical devices with measuring function
Assembly of procedure packs containing non-active medical devices	General non-active, non-implantable medical devices	Non-active ophthalmologic devices
Assembly of procedure packs containing non-active medical devices	General non-active, non-implantable medical devices	Non-active instruments
Assembly of procedure packs containing non-active medical devices	General non-active, non-implantable medical devices	Contraceptive medical devices
Assembly of procedure packs containing non-active medical devices	General non-active, non-implantable medical devices	Non-active medical devices for disinfecting, cleaning and rinsing
Assembly of procedure packs containing non-active medical devices	General non-active, non-implantable medical devices	Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
Assembly of procedure packs containing non-active medical devices	General non-active, non-implantable medical devices	Non-active medical devices for ingestion
Assembly of procedure packs containing non-active medical devices	Non-active implants	Non-active cardiovascular implants
Assembly of procedure packs containing non-active medical devices	Non-active implants	Non-active orthopaedic implants
Assembly of procedure packs containing non-active medical devices	Non-active implants	Non-active functional implants
Assembly of procedure packs containing non-active medical devices	Non-active implants	Non-active soft tissue implants
Assembly of procedure packs containing non-active medical devices	Devices for wound care	Bandages and wound dressings
Assembly of procedure packs containing non-active medical devices	Devices for wound care	Suture material and clamps
Assembly of procedure packs containing non-active medical devices	Devices for wound care	Other medical devices for wound care
Assembly of procedure packs containing non-active medical devices	Non-active dental devices and accessories	Non-active dental devices/equipment and instruments
Assembly of procedure packs containing non-active medical devices	Non-active dental devices and accessories	Dental materials

Assembly of procedure packs containing non-active medical devices	Non-active dental devices and accessories	Dental implants
Assembly of procedure packs containing non-active medical devices	Non-active medical devices other than specified above	n/a
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Devices for extra-corporal circulation, infusion and haemopheresis
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Devices for stimulation or inhibition
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Active surgical devices
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Active ophthalmologic devices
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Active dental devices
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Active devices for disinfection and sterilisation
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Active rehabilitation devices and active prostheses
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Active devices for patient positioning and transport
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
Assembly of procedure packs containing active medical devices (non-implantable)	General active medical devices	Software
Assembly of procedure packs containing active medical devices (non-implantable)	Devices for imaging	Devices utilising ionising rays
Assembly of procedure packs containing active medical devices (non-implantable)	Devices for imaging	Devices utilising non-ionising rays
Assembly of procedure packs containing active medical devices (non-implantable)	Monitoring devices	Monitoring devices of non-vital physiological parameters
Assembly of procedure packs containing active medical devices (non-implantable)	Monitoring devices	Monitoring devices of vital physiological parameters
Assembly of procedure packs containing active medical devices (non-implantable)	Devices for radiation therapy and thermo therapy	Devices utilising ionizing radiation
Assembly of procedure packs containing active medical devices (non-implantable)	Devices for radiation therapy and thermo therapy	Devices utilising non-ionizing radiation

Assembly of procedure packs containing active medical devices (non-implantable)	Devices for radiation therapy and thermo therapy	Devices for hyperthermia/hypothermia
Assembly of procedure packs containing active medical devices (non-implantable)	Devices for radiation therapy and thermo therapy	Devices for (extracorporeal) shockwave therapy (lithotripsy)
Assembly of procedure packs containing active medical devices (non-implantable)	Active (non-implantable) medical devices other than specified above	n/a
Assembly of procedure packs containing active implantable medical devices	General active implantable medical devices	Active implantable medical devices for stimulation / inhibition
Assembly of procedure packs containing active implantable medical devices	General active implantable medical devices	Active implantable medical devices delivering drugs or other substances
Assembly of procedure packs containing active implantable medical devices	General active implantable medical devices	Active implantable medical devices substituting or replacing organ functions
Assembly of procedure packs containing active implantable medical devices	Implantable medical devices other than specified above	n/a
Assembly of procedure packs containing In vitro diagnostic medical devices (IVD)	Reagents and reagent products, calibrators and control materials for: Clinical chemistry Immunochemistry (immunology) Haematology/haemostasis/immunohaematology Microbiology Infectious immunology Histology/cytology Genetic testing	n/a
Assembly of procedure packs containing In vitro diagnostic medical devices (IVD)	In vitro diagnostic instruments and software	n/a
Assembly of procedure packs containing In vitro diagnostic medical devices (IVD)	IVD medical devices other than specified above	n/a
In vitro diagnostic medical devices (IVD)	Reagents and reagent products, calibrators and control materials for: Clinical chemistry Immunochemistry (immunology) Haematology/haemostasis/immunohaematology Microbiology Infectious immunology Histology/cytology Genetic testing	n/a
Active medical devices (non-implantable)	General active medical devices	Software
<i>Note that this schedule refers to ISO 13485:2016 and also includes EN ISO 13485:2016.</i>		