

# ACCREDITATION SCHEDULE



## ORGANISATION

BSCIC Certifications Private Limited

## CERTIFICATE NUMBER

S3931107IF (QMS)                      M3931107IF (Management Systems)

## LOCATIONS AND COUNTRIES COVERED BY ACCREDITATION

Refer to Attachment A

## ACCREDITATION STANDARDS

ISO/IEC 17021:2011– Conformity assessment – Requirements for bodies providing audit and certification of management systems. As guided by:

IAF MD1:2007 – Certification of Multiple Sites Based on Sampling

IAF MD2:2007 – Transfer of Accredited Certification of Management Systems

IAF MD5:2013– Duration of QMS and EMS Audits

**IAF MD 9:2011 - IAF Mandatory Document for the Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485)**

ISO/IEC 27006:2011 Information technology - Security techniques - Requirements for bodies providing audit and certification of information security management systems

**ISO/IEC TS 17021-3:2013 - Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 3: Competence requirements for auditing and certification of quality management systems**

JOINT ACCREDITATION  
SYSTEM OF AUSTRALIA  
AND NEW ZEALAND  
HELPING MARKETS  
WORK BETTER

### Australia

FECCA House  
4 Phipps Close  
Deakin, ACT 2600

PO Box 5634  
Hughes, ACT 2605

Phone: +61 (0)2 6232 2000

### New Zealand

Level 4 Berl House  
108 The Terrace  
Wellington 6143

PO Box 10476  
The Terrace  
Wellington 6143

Phone: +64 (0)4 473 4426

[www.jas-anz.org](http://www.jas-anz.org)

## ISSUE STATUS

Issue: 13

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Signature:  
GM Services

Date: 24<sup>th</sup> December 2014



QMS, EMS, Product

## SCOPE OF ACCREDITATION

(a) QMS and ISMS

ANZSIC CODES		TITLE
0	1	Agriculture
0	2	Services to Agriculture; Hunting and Trapping
0	3	Forestry and Logging
0	4	Commercial Fishing
1	1	Coal Mining
1	2	Oil and Gas Extraction
1	3	Metal Ore Mining
1	4	Other Mining
1	5	Services to Mining
2	1	Food, Beverage and Tobacco Manufacturing
2	2	Textile, Clothing, Footwear and Leather Manufacturing
2	3	Wood and Paper Product Manufacturing
2	4	Printing, Publishing and Recorded Media
2	5	Petroleum, Coal, Chemical and Associated Product Manufacturing
2	6	Non-metallic Mineral Product Manufacturing
2	7	Metal Product Manufacturing
2	8	Machinery and Equipment Manufacturing
2	9	Other Manufacturing
3	6	Electricity and Gas Supply
3	7	Water Supply, Sewerage and Drainage Services
4	1	General Construction
4	2	Construction Trade Services
4	5	Basic Material Wholesaling
4	6	Machinery and Motor Vehicle Wholesaling
4	7	Personal and Household Goods Wholesaling
5	1	Food Retailing
5	2	Personal and Household Goods Retailing
5	3	Motor Vehicle Retailing and Services
5	7	Accommodation, Cafes and Restaurants
6	1	Road Transport
6	2	Rail Transport
6	3	Water Transport
6	4	Air and Space Transport
6	5	Other Transport
6	6	Services to Transport
6	7	Storage
7	1	Communication Services
7	3	Finance
7	4	Insurance
7	5	Services to Finance and Insurance
7	7	Property Services
7	8	Business Services

- 8 1 Government Administration
- 8 2 Defence
- 8 4 Education
- 8 6 Health Services
- 8 7 Community Services
- 9 1 Motion Picture, Radio and Television Services
- 9 2 Libraries, Museums and the Arts
- 9 5 Personal Services
- 9 6 Other Services
- 9 7 Private Households Employing Staff

**Medical Devices Scheme (MD)**

**Scope of Accreditation - IAF MD 8 Medical Devices Technical Areas**

Main Technical Areas	Technical Areas	Recommended
Non-active Medical Devices	General non-active, non-implantable medical devices	Yes
	Non-active implants	Yes
	Devices for wound care	Yes
	Non-active dental devices and accessories	Yes
	Non-active medical devices other than specified above	Yes
Active Medical Devices (Non-implantable)	General active medical devices	Yes
	Devices for imaging	Yes
	Monitoring devices	Yes
	Devices for radiation therapy and thermo therapy	Yes
	Active (non-implantable) medical devices other than specified above	Yes
Active Implantable Medical Devices	General active implantable medical devices	No
	Implantable medical devices other than specified above	No
In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: <ul style="list-style-type: none"> <li>• Clinical Chemistry</li> <li>• Immunochemistry (Immunology)</li> <li>• Haematology/Haemostasis/Immunohaematology</li> <li>• Microbiology</li> <li>• Infectious Innunology</li> <li>• Histology/Cytology</li> <li>• Genetic Testing</li> </ul>	No
	In Vitro Diagnostic Instruments and software	No
	IVD medical devices other than specified above	No



Sterilisation Method for Medical Devices	Ethylene oxide gas sterilisation (EOG)	Yes
	Moist heat	Yes
	Aseptic processing	Yes
	Radiation sterilisation (e.g. gamma, x-ray, electron beam)	Yes
	Sterilisation method other than specified above	Yes
Devices incorporating/utilizing/ specific substances/technologies	Medical devices incorporating medicinal substances	No
	Medical devices utilizing tissues of animal origin	No
	Medical devices incorporating derivatives of human blood	No
	Medical devices utilizing micromechanics	No
	Medical devices utilizing nanomaterials	No
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed	No

**Management Systems Certification Standards**

AS/NZS ISO 9001:2008 – Quality management systems – Requirements

ISO/IEC 27001:2013 - Information technology - Security techniques - Information security management systems – Requirements

ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes

**Note:**

**Accreditation is continuous providing accredited bodies continue to comply with JAS-ANZ requirements. To confirm JAS-ANZ accreditation status, please refer to the JAS-ANZ website at [www.jas-anz.org](http://www.jas-anz.org).**

