

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 <b>8631</b> Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification	<b>BCC Inc.</b>  Issue No: 012 Issue date: 02 Novemeber 2018	
	11/FL, Building 1 Guoyingyuan Xicheng District Beijing PR China 100035	Contact: Shi Jingwei Tel: +86-10-58561816 Fax: +86 -10-58561801 Email: ukas.latd@bcc.com.cn Website: www.bcc.com.cn

### SUMMARY OF ACCREDITED SCOPE

Accredited to provide certification of the following Management Systems Standards and related Sector Schemes as detailed in this schedule:

- [Quality Management Systems \(QMS\) to ISO 9001: 2015](#)
- [Medical Devices - Quality Management Systems \(MD-QMS\) to ISO 13485: 2016](#)



**8631**

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

### Schedule of Accreditation

issued by

### United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**BCC Inc.**

**Issue No:** 012 **Issue date:** 02 November 2018

KEY LOCATION ADDRESS	QMS	MD-QMS
11/FL, Building 1, Guoyingyuan, Xicheng District, Beijing PR China 100035	✓	✓

This Certification Body has demonstrated to UKAS that it has the systems and processes in place to provide the competence and capability, including understanding of local requirements, to manage and issue accredited management systems certification in the country in which it is established and in any other country, for the standards and scopes detailed on this schedule, unless specifically detailed in the individual Management System scope table (*denoted by \**).



8631

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**BCC Inc.**

**Issue No:** 012 **Issue date:** 02 November 2018

**QUALITY MANAGEMENT SYSTEMS**

In accordance with ISO/IEC 17021-1: 2015

**ISO 9001: 2015 Certification**

<b>Accreditation Scope Reference</b> (as defined in IAF ID 1)	<b>Full / Limited Accreditation</b>	<b>Extent of Scope</b>
IAF 3 Food products, beverages and tobacco	Full	
IAF 4 Textiles and textile products	Full	
IAF 12 Chemicals, chemical products and fibres	Full	
IAF 14 Rubber and plastic products	Full	
IAF 15 Non-metallic mineral products	Full	
IAF 16 Concrete, cement, lime, plaster etc	Full	
IAF 17 Basic metals and fabricated metal products	Full	
IAF 18 Machinery and equipment	Full	
IAF 19 Electrical and optical equipment	Full	
IAF 29 Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	Full	
IAF 32 Financial intermediation; real estate; renting	Full	

END



**8631**

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**BCC Inc.**

**Issue No:** 012    **Issue date:** 02 November 2018

**MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS**

In accordance with ISO/IEC 17021-1: 2015

**ISO 13485: 2016 Certification**

<b>IAF Mandatory Scopes of Accreditation Scope Reference</b>	<b>Technical Area</b>
<b>1.1 Non-active Medical Devices</b>	General non-active, non-implantable medical devices
	Non-active implants
	Devices for wound care
	Non-active dental devices and accessories
<b>1.2 Active Medical Devices (Non-Implantable)</b>	General active medical devices
	Monitoring devices
	Devices for radiation therapy and thermo therapy
<b>1.4 In Vitro Diagnostic Medical Devices (IVD)</b>	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 /Immunoematology</li> <li>• Microbiology</li> <li>• Infection Immunology</li> <li>• Histology/cytology</li> <li>• Genetic Testing</li> </ul>
	In vitro diagnostic instruments and software
	IVD medical devices other than specified above



**8631**

Accredited to  
ISO/IEC 17021-1: 2015  
to provide management  
systems certification

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**BCC Inc.**

**Issue No: 012 Issue date: 02 November 2018**

**MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS**

In accordance with ISO/IEC 17021-1: 2015

**ISO 13485: 2016 Certification**

<b>IAF Mandatory Scopes of Accreditation Scope Reference</b>	<b>Technical Area</b>
<b>1.5 Sterilisation Method for Medical Devices</b>	Ethylene oxide gas (EOG)
	Moist heat
	Aseptic processing
	Radiation sterilisation (e.g. gamma, x-ray, electron beam)
	Sterilization method other than specified above
<b>1.7 Parts or Services</b>	Raw materials
	Components
	Subassemblies
	Distribution services
	Maintenance services
	Transportation services
	Other services
<b>END</b>	