



## **ISO CERTIFICATION & REGULATORY COMPLIANCE**

August 2023

Products supplied to customers in Israel by Syntezza Bioscience Limited (“Syntezza”) are produced exclusively under ISO compliant conditions by our manufacturing partners:

- Integrated DNA Technologies Inc. – Coralville, Iowa USA
- Integrated DNA Technologies BVBA – Leuven, Belgium
- Bio Basic Inc. - Markham, Ontario, Canada
- TriLink Biotechnologies – San Diego, California USA

Sanger DNA Sequencing and Whole Plasmid Sequencing are performed exclusively under ISO 9001:2015 compliant conditions at the facilities of Macrogen Europe BV in Amsterdam, Netherlands.

Next Generation Sequencing services (NGS) performed at the BL-2 facility of Syntezza are for Research Use Only and are not ISO compliant.

The following products supplied by Syntezza are not manufactured under ISO compliant conditions: PCR-Ready S, PCR-Ready Y, D-Tail, the research products of GenTegra LLC and of GRiSP.

Copies of the active ISO certificates of our manufacturing and sequencing partners are attached.



By Royal Charter

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**Integrated DNA Technologies**  
1710 Commercial Park  
Coralville  
Iowa  
52241  
USA

Holds Certificate Number:

FM 513219

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The manufacturing/processing services, customer support, and sales/distribution for custom, synthetic nucleic acid and associated reagent/consumable products for molecular biology applications, including (but not limited to) qPCR, sequencing, synthetic biology and functional genomics as a material for molecular in-vitro diagnostic devices and laboratory developed tests.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2008-04-07

Latest Revision Date: 2023-08-02

Effective Date: 2023-08-09

Expiry Date: 2026-08-08



Page: 1 of 2

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands  
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.  
Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.

Certificate No: **FM 88954**

Location	Registered Activities
Integrated DNA Technologies 1710 Commercial Park Coralville Iowa 52241 USA	The manufacturing/processing services, customer support, and sales/distribution for custom, synthetic nucleic acid and associated reagent/consumable products for molecular biology applications, including (but not limited to) qPCR, sequencing, synthetic biology and functional genomics.
Integrated DNA Technologies West Coast Operations 6828 Nancy Ridge Dr. Suites 400 & 300 San Diego California 92121 USA	The manufacturing/processing services, customer support, and sales/distribution for custom, synthetic nucleic acid and associated reagent/consumable products for molecular biology applications, including (but not limited to) qPCR, sequencing, synthetic biology and functional genomics.
Integrated DNA Technologies BVBA Interleuvenlaan 12A Leuven B-3001 Belgium	The manufacturing/processing services, customer support, and sales/distribution for custom, synthetic nucleic acid and associated reagent/consumable products for molecular biology applications, including (but not limited to) qPCR, sequencing, synthetic biology and functional genomics.
Advanced Solutions Center 2600 Crosspark Road Coralville Iowa 52241 USA	Process software design and development.
BioVentures Center 2500 Cross Park Road Coralville Iowa 52241 USA	Manufacturing/Processing Services; High Throughput Product Formulation (HPF)/Custom Build Services (CBS).
Integrated DNA Technologies Pte. Ltd. 41 Science Park Road #01-28 The Gemini Singapore Science Park II 117610 Singapore	The manufacturing/processing services, customer support, and sales/distribution for custom, synthetic nucleic acid and associated reagent/consumable products for molecular biology applications, including (but not limited to) qPCR, sequencing, synthetic biology and functional genomics.

Original Registration Date: 2005-08-09

Effective Date: 2023-08-09

Latest Revision Date: 2023-08-02

Expiry Date: 2026-08-08

Page: 2 of 3

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To be read in conjunction with the scope above or the attached appendix.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No: **FM 88954**

Location	Registered Activities
SD- Digital Biology Facility 5626 Oberlin Dr, Suite #100 San Diego California 92121 USA	Manufacturing/processing services for custom, synthetic nucleic acid and associated reagent/consumable products for molecular biology applications, including qPCR, sequencing, synthetic biology and functional genomics.
Integrated DNA Technologies, Inc 2660 CrossPark Rd Coralville Iowa 52241 USA	Manufacturing/processing services for Synthetic Biology applications.



Original Registration Date: 2005-08-09

Effective Date: 2023-08-09

Latest Revision Date: 2023-08-02

Expiry Date: 2026-08-08

Page: 3 of 3

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Holds Certificate Number:

FM 513219

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The manufacturing/processing services, customer support, and sales/distribution for custom, synthetic nucleic acid and associated reagent/consumable products for molecular biology applications, including (but not limited to) qPCR, sequencing, synthetic biology and functional genomics as a material for molecular in-vitro diagnostic devices and laboratory developed tests.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2008-04-07

Effective Date: 2023-08-09

Latest Revision Date: 2023-08-02

Expiry Date: 2026-08-08



Page: 1 of 2

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Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.

Certificate No: FM 513219

Location	Registered Activities
Integrated DNA Technologies 1710 Commercial Park Coralville Iowa 52241 USA	The manufacturing/processing services, customer support, and sales/distribution for custom, synthetic nucleic acid and associated reagent/consumable products for molecular biology applications, including (but not limited to) qPCR, sequencing, synthetic biology and functional genomics as a material for molecular in-vitro diagnostic devices and laboratory developed tests.
Integrated DNA Technologies BVBA Interleuvenlaan 12A Leuven B-3001 Belgium	Manufacturing, Customer Support, Sales and Distribution.
Advanced Solutions Center 2600 Crosspark Road Coralville Iowa 52241 USA	Process software design and development.
BioVentures Center 2500 Cross Park Road Coralville Iowa 52241 USA	Manufacturing/Processing Services; High Throughput Product Formulation (HPF)/Custom Build Services (CBS).
Integrated DNA Technologies, Inc 2660 CrossPark Rd Coralville Iowa 52241 USA	Manufacturing/processing services for Synthetic Biology applications.

Original Registration Date: 2008-04-07

Effective Date: 2023-08-09

Latest Revision Date: 2023-08-02

Expiry Date: 2026-08-08

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Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.

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# Certificate of Approval

This is to certify that the Management System of:

## TriLink BioTechnologies

10770 Wateridge Circle, Suite 200, San Diego, CA, 92121, United States

has been approved by LRQA to the following standards:

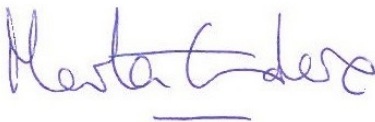
### ISO 9001:2015

Approval number(s): ISO 9001 – 0013380

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

#### The scope of this approval is applicable to:

The Design, Manufacture, and Delivery of Complex and Highly-Modified Nucleic Acids and Supporting Reagents.



**Marta Escudero**

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Regional Director, United Kingdom and Americas (UKAM)

Issued by: LRQA Limited



# Certificate Schedule

Location	Activities
10770 Wateridge Circle, Suite 200, San Diego, CA, 92121, United States	<b>ISO 9001:2015</b> The Design, Manufacture, and Delivery of Complex and Highly-Modified Nucleic Acids and Supporting Reagents.
5717 Pacific Center Boulevard, San Diego, CA, 92121, United States	<b>ISO 9001:2015</b> Storage of Supplies.







Certification Partner Global  
ISO 9001 : 2015

# CERTIFICATE OF REGISTRATION

THIS IS TO CERTIFY THAT THE  
QUALITY MANAGEMENT SYSTEM OF

## Bio Basic Canada Inc.

**20 Konrad Crescent  
Markham  
Ontario L3R 8T4  
CANADA**

Has been assessed and registered as complying with the requirements of the International Standard shown above for the following Goods and Services. Further clarifications regarding the scope of this certificate and the applicability of the requirements of

**ISO 9001 : 2015**

may be obtained by consulting the certificate issuer.

**Manufacturer and Supplier of Biochemical and Research Products  
and Services - Excluding Design and Development. Previously  
certified by ISC to ISO 9001:2000 on 19th Dec 2008.**



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

Tony Wilde  
Group Chairman

Registration Number:	QMS/15/R01/0027
Original 9001 Registration Date:	19-Dec-2008
Current Registration Date:	19-Sep-2018
Recertification Date:	30-Jan-2023
Expiry Date:	20-Dec-2025
Amendment Date:	

### Certification Partner Global

An Australian Owned Company  
License # 1150/2011 CC (previously known as ISC Global),  
Level 03, Boulevard Plaza, Tower 1, Downtown Dubai, Dubai, UAE

The Status and Validity of this Certificate maybe verified in real time by scanning the adjacent QR Code.

This certificate is valid until the Expiry Date shown on the condition that audits are conducted each year and paid for as per the Certification Agreement. Should this condition not be met, cancellation procedures will be initiated, and the cancellation status will be revealed when the QR Code is scanned.

This Certificate remains the property of the Certificate Issuer and must be returned upon request. It must not be altered in any way. Intentional misuse of this certificate will result in cancellation without prior notification



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Macrogen  
10F, World Merdiang 1 Cha  
254, Beotkkot-ro  
Geumcheon-gu  
Seoul  
08511  
Republic of Korea

Holds Certificate No:

**FM 89418**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The provision of the DNA sequencing service, the next generation sequencing service and the DNA analysis service, and the DNA chip service, the oligo synthesis service, genome engineering mouse(transgenic, knock-out and knock-in) and CRISPR(Clustered Regularly Interspaced Short Palindromic Repeats) product services.

For and on behalf of BSI:

Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 2004-10-26

Effective Date: 2022-10-24

Latest Revision Date:

Expiry Date: 2025-10-23

Page: 1 of 2



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