

TTAN BIOTECH LTD





Office: 903-909, 9th Floor, Bigjos Tower, Netaji Subhash Place, Delhi-110034, India Tel.: 011-27355742, 71239900 (44 Lines) | Fax: +91-11-47619811 | CIN: L74999RJ1992PLC013387

EC DECLARATION OF CONFORMITY

1. Manufacturer: Titan Biotech Limited.

Address: A-902A, RIICO INDUSTRIAL AREA, Phase III, Bhiwadi-301019.

2. Authorized European Representative: MedNet GmbH

Address: Borkskasse 10, 48163 Muenster.

3. Product:

S.NO	PRODUCT NAME	
1.	Dehydrated Culture Media	
2.	Additives for DCM (Growth supplements, selective agents,)	

- 4. Number of Total Products: 222 (Attachment 1)
- 5. The product described above is in conformity with:

TITLE	DOCUMENT NUMBER
In vitro Diagnostic Medical Devices Directive	98/79/EC

6. Additional Information:

The products are not covered by Annex II of the 98/79/EC directive.

Conformity assessment was performed according to Annex I and Annex III of the 98/79/EC directive.

7. Applied Standards To Prove Conformity:

ISO 13485:2016: Quality Systems-Requirements for regulatory purposes (Attachment 2)

ISO 9001:2015: Quality Management System (Attachment 3)

ISO 11133:2014: Quality Assurance-Culture Media (Attachment 4)

- an undertaking by the manufacturer to fulfil the obligations imposed by the

quality system approved

R.O. & Works: Unit I: A-902 A, RIICO Industrial Area, Phase-III, Bhiwadi-301019, Rajastna

Unit II: E-540, Industrial Area, Chopanki, Bhiwadi-301019, Rajasthan

E-mail: marketing@titanbiotechltd.com

Website: www.titanbiotechltd.com | www.titanmedia.in



TITAN BIOTECH LTD.

AN ISO 9001:2015 CERTIFIED COMPANY



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8. Company undertakes to keep up to date systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature and risk in relation of the product.

9. Company undertakes to notify immediately any malfunction/deterioration of the performance of the product to the appropriate authority and shall recall such products already placed in the market.

10. Company is exclusively responsible for the declaration of conformity.

For Eitan Biotech Ltd.

Dated:29-01-2017

(Managing Director)

Suresh Singla



CERTIFICATE OF COMPLIANCE



INTERNATIONAL CERTIFICATION SERVICES PVT. LTD.

This is to certify that the QUALITY MANAGEMENT SYSTEM of

TITAN BIOTECH LIMITED

A-902-A, RIICO Industrial Area, Phase III, Bhiwadi - 301 019, Rajasthan, India.

has been assessed and registered as complying with the requirements of the following International Standard:

ISO 9001:2015

The Quality Management System applicable to:

Scope: Manufacture And Export of Protein Hydrolysate, Peptone, Biological Extracts, Microbiological Dehydrated Culture Media, Ready To Use Liquid Media, Biological Bases, Anti Microbial Susceptibility Disk, Bacteriological Differential Reagent, Laboratory Chemicals & Reagents.



Registration No.
Registered Date
Reassessment Date
Issue Date
Expiry Date

: RQ91/1222

: 25th October, 2002

: 27th November, 2017

: 28th November, 2017

: 24th October, 2020,



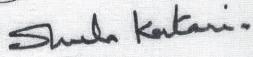




www.jas-anz.org/register







Director International Certification Services

Accredited by Joint Accreditation System of Australia and New Zealand

Validity of this certificate is based on periodic audits of the management system defined by the above scope and is contingent upon prompt, written notification of significant changes to the management system and/or its components thereof shall be immediately communicated to ICS.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained at www.icsasian.com

CERTIFICATE OF COMPLIANCE



INTERNATIONAL CERTIFICATION SERVICES PVT. LTD.

This is to certify that the QUALITY ASSURANCE SYSTEM of

TITAN BIOTECH LIMITED

A-902, A, RIICO Industrial Area, Phase - III, Bhiwadi - 301 019, Rajasthan, India.

has been assessed and registered as complying with the requirements of the following International Standard:

ISO 11133: 2014

The Microbiology of Food, Animal feed and Water - preparation, production, storage and performance testing of culture media applicable to :

Scope:

Manufacturing and Supply of Microbiological Dehydrated Culture Media and Supplements, Plant Tissue Culture Media, Ready To Use Media, Biological Media Bases, Antimicrobial Susceptibility Disks, Bacteriological Differentiation Reagents and Kits



Registration No. Registered Date **Expiry Date**

: ROMF91/9610 : 02nd June, 2017

: 01st June, 2020

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Director International Certification Services Pvt. Ltd.

Validity of this certificate is based on periodic audits of the management system defined by the above scope and is contingent upon prompt, written notification of significant changes to the management system and/or its components thereof shall be Further clarifications regarding the scope of this certificate and the applicability of ISO 11133:2014 requirements may be

obtained at www.icsasian.com

CERTIFICATE OF COMPLIANCE



INTERNATIONAL CERTIFICATION SERVICES PVT. LTD.

This is to certify that the QUALITY ASSURANCE SYSTEM of

TITAN BIOTECH LIMITED

A-902, A, RIICO Industrial Area, Phase - III, Bhiwadi - 301 019, Rajasthan, India.

has been assessed and registered as complying with the requirements of the following International Standard:

ISO 13485: 2016

The Quality Assurance System applicable to :

Scope:

Manufacturing And Supply Of Microbiological Dehydrated Culture Media, Ready To Use Media And Its Bases. **Bacteriological** Disk, Susceptibility **Antimicrobial Differentiation Reagent.**



: RQMD91/6791 Registration No. Registered Date Reassessment Date : 02nd January, 2017 **Issue Date**

Expiry Date

: 27th December, 2010

: 03rd January, 2017 : 26th December, 2019



Managing Director International Certification Services

Validity of this certificate is based on periodic audits of the management system defined by the above scope and is contingent upon prompt, written notification of significant changes to the management system and/or its components thereof shall be

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained at www.icsasian.com



TITAN BIOTECH LID.

AN ISO 9001:2008 CERTIFIED COMPANY



Corp.Off.: 303-305 Lusa Tower, Azadpur Comm. Complex, Delhi-33, India
Ph.: 011-47020100, 27677960, 27675668, 27674615 | Fax: +91-11-47619811 | CIN: L74999RJ1992PLC013387

TO WHOM IT MAY CONCERN

We M/S-Titan Biotech Ltd, India manufacturer & Exporter of Biological Products, Dehydrated Microbiological Culture Media & Biological Media Bases, Plant Tissue Culture Media and Laboratory Chemicals duly organised under the laws of India and having its Corporate office at -A-2/3,303-305, Lusa Tower, Azadpur, Commercial Complex, New Delhi, 110033 & Registered office & Works at A-902A, RIICO Industrial Area, Phase-III, Bhiwadi-301019 (Raj.) India does hereby authorize:

M/s SRL "Mic-Tan" c/f 1002600038282 CUIO 20149744

Moldova, the city: Chişînău, str. Independenței 44-34 cod IBAN (EURO): MD34FT222480100002420978

As our authorized agent to Import our products Like (Biological Products, Dehydrated Microbiological Culture Media & Biological Media Bases, Plant Tissue Culture Media and Laboratory Chemicals) for Moldova market and sale&promote it for same market. This agreement is effective for one year from the date of this letter and will extend automatically. Termination of this agreement without cause, if so desired by either party, should be notified with 60 days notice by an official document (Written Notice)

For Thinh Biojech Limited

Export Manager

Date: 07/07/2017

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