



# TITAN BIOTECH LTD.

AN ISO 9001:2015 CERTIFIED COMPANY



Office : 903-909, 9<sup>th</sup> 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, Rajasthan

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

**E-mail:** marketing@titanbiotechltd.com

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



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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 Titan Biotech Ltd.

Dated: 29-01-2017

  
Suresh Singla  
(Managing Director)

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