



EC Declaration of Conformity

1.Manufacturer: Titan Biotech Limited

Address: A-902-A, RIICO INDUSTRIAL AREA, PHASE-3 BHIWADI-301019

2.Authorized European Representative: MedNet GmbH

Address: Borkskasse 10, 48163 Muenster

3. Product:

S.NO	Product Name
1.	Dehydrated Culture Media
2.	Additive for DCM(Selective Agent, Growth Supply,..)
3.	Viral Transport Kit
4.	Antibiotic Disc

4. Number of total products:

5. The Product described above is conformity with:

Title	Document Number
In vitro Diagnostics Medicare Devices Directives	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 –Requirement for Regulatory Purposes. (Attachment 1)

ISO 9001:2015: Quality Management System (Attachment 2)

ISO 11133 :2014: Quality Assurance- Culture Media (Attachment 3)

An undertaking by the manufacturer to fulfill the obligation imposed by the quality system approved.

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 correctives actions taking account of the nature and risk in details in relation of the product.

9. Company undertakes to notify immediately any malfunction/deterioration of the performance of the product of 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 LIMITED

Authorized Signatory

