Contract for European Authorized Representation
(*in-vitro* Diagnostic Medical Devices)

between

MedNet EC-REP GmbH,
Borkstrasse 10,
48163 Münster,
Germany,

Digitally signed by Pîslaru Rodica
Date: 2022.07.26 13:36:39 EEST
Reason: MoldSign Signature
Location: Moldova

(hereinafter referred to as **MedNet**)

and

Titan Biotech Ltd.
A-902A, RIICO Industrial Area Phase-III,
Bhiwadi - 301019 (Raj.) India

(hereinafter referred to as **Manufacturer**)

Manufacturer is a company established outside the European Union (EU) and intends placing on the market in-vitro diagnostic medical devices bearing a CE mark.

MedNet undertakes to provide to the **Manufacturer** authorized representation services as required under Article 11 (1) of the Regulation (EU) 2017/746 on in-vitro diagnostic medical devices (here referred to as **IVDR**) and for the remaining transition time according to the Directive 98/79/EC on in-vitro diagnostic medical devices (here referred to as **IVDD**).

NOW THEREFORE, according to Article 11 (2) **IVDR** the parties hereto hereby agree as follows:

§ 1 Object and Scope

(1) **Manufacturer** appoints **MedNet** to be its single European Authorized Representative (hereinafter referred to as **AR**) as defined in Article 2 (25) **IVDR** in the EU for all in-vitro diagnostic medical devices as listed in **Attachment A** hereto (hereinafter referred to as "**Product**" or "**Products**"). The **Products** are in-vitro diagnostic medical devices within the definition in accordance to Article 2 (2) and Article 2 (4) **IVDR** and shall be classified according to Annex VIII of the **IVDR**. In **Attachment A** hereto, the **Products** and their classification are listed.

(2) **MedNet** accepts the appointment as **AR** under the **IVDR** (and for the interim period under **IVDD**).

(3) This contract supersedes any prior agreements between the parties regarding to European Authorized Representation.

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§ 2 Information on Economic Operators

(1) The **Products** shall be placed on the EU-market under **Manufacturer**'s own name as the legal **Manufacturer** in line with Article 2 (23) **IVDR**.

(2) Additionally, **MedNet** shall be added on the label, packaging and instructions for use of the **Products** as **AR** with its name, registered place of business and the address at which **MedNet** can be contacted.

(3) Furthermore, according to Article 13 (3) **IVDR** the relevant **Importer** of the **Product** shall be indicated beside the **Manufacturer** and **MedNet** on the relevant **Products** or on its packaging or in a document accompanying each **Product** as European **Importer** with its name, registered trade name, registered place of business and the address at which the **Importer** can be contacted.

(4) Upon signing this contract, **Manufacturer** will provide **MedNet** with a detailed list of all **Importers** of the **Products** listed in **Attachment A**. The **Manufacturer** commits to provide an updated list whenever any change occurs (including addition of new importers) and at least once a year. The information will be provided to **MedNet** in a template to be provided by **MedNet**.

§ 3 Obligations and Responsibilities of the Manufacturer

(1) The **Manufacturer** (as the legal **Manufacturer**) shall be responsible for the conformity assessment procedure of the **Products** in accordance with Article 48 **IVDR** and all other applicable European laws, rules and regulations, relevant to the **Products**. **Manufacturer** will provide a proper label and instructions for use.

(2) The **Manufacturer** shall keep records for full traceability of all sales of **Products** made into the EU-market for at least 10 years after the last device covered by the relevant EU declaration of conformity has been placed on the market. The **Manufacturer** shall provide these records to **MedNet** no later than 2 working days after a request to receive such records from any EU Competent Authority.

(3) The **Manufacturer** shall enable **MedNet** to effectively verify in justified cases to EU Competent Authorities, notified bodies or in court that

a. each **Product** has been CE marked according to Article 18 **IVDR**,
b. the EU declaration of conformity has been drawn up according to Article 17 **IVDR**,
c. the technical documentation has been drawn up according to Annexes II and III of the **IVDR**,
d. an appropriate conformity assessment procedure has been carried out according to Article 48 **IVDR**,
e. each **Product** is accompanied by the information to be supplied by the **Manufacturer** in accordance with section 20 of Annex I of the **IVDR**,
f. the **Importers** have complied with the requirements set out in Article 13 **IVDR**,
g. an UDI has been assigned and implemented by the **Manufacturer**,

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h. the **Manufacturer** fulfilled its registration obligations under Articles 26-30 **IVDR** when **EUDAMED** becomes available.

(4) The **Manufacturer** shall provide to **MedNet**

a. the EU declaration of conformity,
b. a copy of the relevant certificate(s) according to Article 51 **IVDR**, including any amendments and supplements, issued in the course of a conformity assessment procedure by the **Manufacturer**'s notified body,
c. a copy of the technical documentation immediately upon request,
d. all information to fulfil and comply with the registration obligations,
e. all information and documentation necessary to demonstrate the conformity of a **Product**, in English,
f. samples, or access to a **Product** for verification by any EU Competent Authority on authority's request for sample or access to the **Product**,
g. at least once a year or if any change occurred after last list was sent to **MedNet** a current list of **Importer's** and distributor's contact details in the EU,
h. all documents required by the latest medical device guideline **MEDDEV 2.5/10**,
i. written notice of any change in the above (§3 (4) a-h).

(5) The **Manufacturer** shall inform **MedNet**

a. immediately when a **Product** will no longer be manufactured,
b. of any **Product** changes that may influence the registration,
c. immediately in case of suspension or abrogation or refusal of extension or renewal of certificates issued by the **Manufacturers** notified body,
d. by written notice of any clinical studies and/or post marketing studies performed with **Products** in the EU [Clinical studies/Post Marketing studies may require additional contracts to define responsibilities and payment conditions if applicable],
e. about all reportable serious incidents and FSCAs (Field Safety Corrective Action).

(6) The **Manufacturer** shall establish and have available a **Person Responsible for Regulatory Compliance** according to Article 15 **IVDR** (hereinafter referred to as "**PRRC**"), who has the required qualification according to Article 15 (1) **IVDR**. Manufacturer shall follow the guidance of MDCG 2019-7 Guidance on Article 15 of the Medical Device Regulation (MDR) and in-vitro Diagnostic Device Regulation (IVDR) regarding a "person responsible for regulatory compliance" (**PRRC**).

§ 4 Responsibilities and Obligations of MedNet

(1) **MedNet** shall verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the **Manufacturer**.

(2) **MedNet** shall be responsible for

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a. complying with and performing the registration obligations laid down in Article 28 **IVDR.** Until **EUDAMED** is operational, **MedNet** will comply to the registration guidance of its local Competent Authority.
b. response to a request of the EU Competent Authorities and provide the authorities with all the information and documentation requested,
c. forwarding to the **Manufacturer** any request by any EU Competent Authority,
d. cooperate with the **Manufacturer** and the EU Competent Authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by a **Product,**
e. inform the **Manufacturer** about complaints and reports from **importers,** distributors, healthcare professionals, patients and users about suspected incidents related to a **Product,** immediately, and
f. grant full access to its premises and to the relevant documentation with regard to the **Products** in case of an audit performed by **Manufacturer**'s notified body.

(3) **MedNet** shall establish and have permanently and continuously at its disposal a **PRRC** who has the respective qualification.

(4) Upon request, **MedNet** will additionally provide the following services to the **Manufacturer**:

a. **MedNet** will help the **Manufacturer** in deciding when an incident is reportable,
b. **MedNet** will assist the **Manufacturer** in preparing reports regarding incidents and FSCA,
c. **MedNet** will provide guidance to the **Manufacturer** in the preparation of EC declarations of conformity,
d. **MedNet** will provide guidance to the **Manufacturer** as to labeling and language requirements in EU member states, and
e. **MedNet** will provide **Manufacturer** from time to time, when appropriate, an update on the regulation.

(5) **MedNet** will perform additional registrations upon request in countries requiring such additional registrations. Additional fees will apply according to **§ 9 Fees and Payment Terms**. **MedNet** will keep a current list of countries requiring additional registrations.

§ 5 Post Market Surveillance and Vigilance

(1) The **Manufacturer** shall establish and maintain a post-market surveillance system according to Articles 78-81 **IVDR** in which all relevant data on the quality, clinical performance and safety of the **Products** throughout their entire lifetime can be actively and systematically gathered and analyzed by the **Manufacturer**.

(2) The **Manufacturer** shall establish and maintain a vigilance system according to Articles 82-84 **IVDR**. Part of such system shall include the records, communications and any received reports about suspected incidents related to the **Product** or relating to similar in-vitro diagnostic medical devices in the EU-Market.

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(3) With regard to the **Products**, **MedNet** shall keep a register of reports it receives of non-conforming **Products**, and inform the **Manufacturer** without delay of such reports. **MedNet** will also keep records of FSCA relating to the **Products**.

(4) In case **Manufacturer** decides to perform a FSCA on the **Products**, **MedNet** shall support such actions actively. **MedNet** shall not perform a FSCA on the **Products** on its own, unless a non-conformity of the **Product** or a serious risk requires immediate action, or such FSCA was agreed upon by the **Manufacturer** in advance, or it is ordered to do so by a German Competent Authority.

(5) **Manufacturer** will bear the costs of any FSCA and refund **MedNet**'s expenses for supporting or performing a FSCA according to (4) with regard to the Products.

(6) Unless required by national laws otherwise, **MedNet** shall lead the correspondence with EU Competent Authorities.

(7) **Manufacturer** commits to cooperate with **MedNet** in all market surveillance or vigilance issues and shall forward any documents, information or data to **MedNet** in case such information was send to **Manufacturer** by EU Competent Authorities, directly.

§ 6 Product Liability

(1) In the event that any claim for a physical, property or financial damage is made against **MedNet** by any third party as a result of any defect in a **Product** or any infringement of third-party rights by a **Product**, the **Manufacturer** shall hold **MedNet** harmless and shall indemnify **MedNet** from any and all claims connected therewith, including attorney's fees incurred by **MedNet** to defend such claims (hereinafter referred to as "**Product Liability**").

(2) The **Manufacturer** hereby undertakes to establish a **Product Liability** insurance with a coverage appropriate to the risk associated with the **Products** and the volume of sales in the EU, which shall cover **Product Liability** cases related to the **Products** and shall remain in force while this contract remains in force and effect or for at least 10 (ten) years after the delivery of the last **Product**, whichever date may be later. Such insurance shall cover **MedNet** in its role as **AR** against all potential **Product Liability** claims by a third party.

(3) Upon request by **MedNet**, the **Manufacturer** shall submit a copy of the insurance policy in the English language.

§ 7 Confidentiality

(1) **MedNet** agrees to treat all information and documentation with which it comes into contact, with the utmost confidentiality. **MedNet** commits not to pass information received from the **Manufacturer** to third parties (other than EU Competent Authorities), without prior written approval of the **Manufacturer**.

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(2) **MedNet** agrees to sign the **Manufacturer**'s Non-Disclosure Agreement (**NDA**), as part of the implementation of this contract with the exception that such **NDA** by default will not restrict the obligations of **MedNet** under this contract.

§ 8 Term and termination

(1) This contract shall enter into full force and effect when duly signed by both of the parties. The effective date is the date of the contract draft signed by the **Manufacturer** (**19.10.2021**). This contract will stay in effect until it is terminated by one of the parties according to this section.

(2) This contract may be terminated by either of the parties by ordinary termination with 3 months' notice as of the end of a calendar year (31st December).

(3) Notwithstanding, each party shall have the right to extraordinary termination on serious grounds.
Not receiving payment according to **§ 9 Fees and payment** constitutes a serious violation and may lead to an immediate termination.

(4) **Manufacturer** hereby acknowledges it is aware of the fact that under Article 11 (3) (h) of the **IVDR**, **MedNet** must terminate the agreement, if **MedNet** becomes aware that **Manufacturer** does not comply to its obligations according to **IVDR**. Upon **MedNet** becoming aware of a **IVDR** violation by the **Manufacturer**, **MedNet** will inform the **Manufacturer** in writing of this agreement being suspended. **Manufacturer** will respond within 3 working days and provide a detailed plan with a timeline to remedy the non-conformance, or explains why the observation made by **MedNet** is wrong. **MedNet** will respond within 5 working days. If **MedNet** disagrees with the **Manufacturer**, **MedNet** terminates the contract.

(5) Any termination of this contract must be in writing.

(6) Upon the termination of this contract the **Manufacturer** agrees not to place any **Products** on the market with the name and address of **MedNet**. The name and address shall be removed from all **Products**, packaging, labeling, instructions for use, advertising material and the Declaration(s) of Conformity.

(7) Upon termination **MedNet** shall immediately notify the relevant EU Competent Authorities, notified body of the **Manufacturer** and / or **EUDAMED** as applicable, that **MedNet** is no longer the AR of the **Manufacturer**. Upon said notification, **MedNet** shall no longer be responsible or in any way liable for the **Products** of the **Manufacturer** to be placed on the market.

§ 9 Fees and payments

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(1) The annual fee to be paid by the **Manufacturer** is **2475 EURO**.

(2) For additional notifications upon request, which are, upon signing this contract, required in other EU countries, an additional fee will be charged per **Product** in each country. MedNet will provide the current price for such a notification at the time it is requested to do so by the **Manufacturer**.

(3) Payment terms:
The first annual payment is due within 30 days of signing the agreement.

Subsequent years are to be invoiced on an annual basis, to be paid within 30 days of the date of the invoice.

Payment will be made directly to **MedNet** in EURO. Payment is excluding VAT or bank charges related to the bank transfer.

The above fee covers the services indicated in this contract only. Additional charges that may be inflicted by the EU Competent Authorities or by new EC legislation will be fully covered by the **Manufacturer**.

§ 10 Contact Persons

(1) Each party will provide the other party with the details of the primary contact (name, phone no., email address) for fulfilling the agreement.

(2) The **Manufacturer** will provide details of two contact persons available in case of emergency (name, cell phone no. and email address).
MedNet will provide the details of a cell phone number available 24/7 for vigilance case (serious public health threat, or unanticipated serious deterioration in state of health) emergency contact.

(3) Each party will provide the other party with the details of the **PRRC**.

(4) Each party will inform the other party immediately and without delay of any change in the above (§ 10 (1), 10 (2), 10 (3)).

§ 11 Changing AR

(1) Should the **Manufacturer** wish to change from **MedNet** to another **AR**, the following must be followed.

(2) Termination of this agreement according to **§ 8 Term and termination**,

(3) provide **MedNet** with the details of the new **AR** and the date it takes over responsibility,

(4) provide **MedNet** with the requested date of registration withdrawal, if this date is prior to the last date of this agreement being in effect.

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(5) **MedNet** commits to comply with Article 12 (d) **IVDR** to all **Products** bearing **MedNet**'s name already placed in the EU market at the time of termination, at no additional payment.

(6) The **Manufacturer** commits to make available all additional documents as described in **§ 3 (2) Obligations and Responsibilities of the Manufacturer** for 10 years following the termination.

§ 12 Transition Period Provisions

(1) Until May 26th, 2022 **Manufacturer** may comply with the relevant **IVDD** provisions instead of **IVDR** provisions laid out in this contract.

(2) The **Manufacturer** of **Products** falling under Article 110 (3) **IVDR** may continue using their **IVDD** documentation until the end of the transition period respectively the expiring date of the relevant certificate.
However, the requirements of the **IVDR** relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply.

§ 13 General Provisions

(1) This contract in its entirety is governed by and construed with the German law.

(2) The local courts at **MedNet**'s registered place of business shall have the exclusive jurisdiction for legal disputes arising from or in connection with this contract.

(3) In case a provision of this contract may be or become partly or wholly invalid or not executable or if there is prove to be an omission therein, this shall not affect the validity of the remaining provisions. Instead of the invalid or not executable provision, a valid provision shall be deemed agreed which comes closest to achieving the purpose of the invalid or not executable one. In the event of an omission, that provision shall be deemed agreed which would have been agreed in accordance with the sense and purpose of this contract, had the parties given the matter consideration from the outset.

For MedNet		**For the Manufacturer**	
Name	Matthias Heinz, Ole Stein	Name	Mr Suresh Chand Singla
Position	Managing Directors	Position	Managing Director
Date	21.10.2021	Date	19.10.2021
Signature		Signature	

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Attachment A

Number	Product(s)	Risk Class (Annex VIII IVDR)	Risk Class (Annex II IVDD)
1	Dehydrated Culture Media	Class A	Other device not listed under Annex II and self-testing.
2	Additives for DCM (Growth supplements, selective agents, ...)	Class A	Other device not listed under Annex II and self-testing.
3	Antibiotic Discs	Class A	Other device not listed under Annex II and self-testing.
4	Viral Transport Kit / Molecular Transport Kit / Universal Transport Kit	Class A	Other device not listed under Annex II and self-testing.
5	Ready To Use Media (Prepared Culture Media)	Class A	Other device not listed under Annexure II and self- testing

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