UK RESPONSIBLE PERSON AGREEMENT

8th of February 2021

We are pleased to confirm **Viamed Ltd., 15 Station Road, Cross Hills, Keighley, BD20 7DT West Yorkshire, United Kingdom** as the designated UK Responsible Person (Authorized Representative) of **MIPM Mammendorfer Institut für Physik und Medizin GmbH (MIPM), Oskar-von-Miller Str. 6, 82291 Mammendorf, GERMANY ("Manufacturer")**.

The Manufacturer and the UK Responsible Person will be individually referred to as a "Party" and jointly, the "Parties".

The UK Responsible Person shall perform the following tasks:

(1) 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) Keeping available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the Medicines and Healthcare Products Regulatory Agency (MHRA);

(3) Comply with his registration obligations laid down in the UK MDR 2002 as amended by the UK MDR 2019 any applicable laws ;

(4) In response to a request from MHRA, provide that MHRA with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

(5) Forward to Manufacturer any request by MHRA, or access to a device and verify that the MHRA receives the samples or is given access to the device;

(6) Cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(7) Immediately inform Manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

(8) In case of incidents known first by Manufacturer, the UK Responsible Person will be immediately informed and will immediately perform with Manufacturer the analysis of the incident. If considered as reportable UK Responsible Person will write and send to MHRA, within the time lines defined by the applicable regulation, the initial report including Manufacturer's actions if available such as sample analysis, analysis of historic lot records and potential corrective actions with target. As soon as incident investigation by Manufacturer is completed, the UK Responsible Person writes and sends the final incident report. In any case, the UK Responsible Person submits these reports to Manufacturer for preliminary approval. The UK Responsible Person will keep these records available for inspection by MHRA;

(9) In case of Field Safety Corrective Action (FSCA) decided by Manufacturer, the UK Responsible Person will request all the necessary information allowing FSCA initial reporting to the MHRA. The UK Responsible Person will forward to Manufacturer any request from the MHRA and will transmit the answers to MHRA. As soon as the FSCA is considered as completed by Manufacturer, the UK Responsible Person writes and sends the final FSCA report to the MHRA. In any case, the UK Responsible Person submits these reports to Manufacturer for preliminary approval. The UK Responsible Person will keep these records available for inspection by MHRA.

(10) This Agreement shall enter in force for a period of one (1) year. This Agreement may be terminated by either Party at any date after the first twelve-month period by written notification to the other Party ninety (90) days prior to the indicated termination date. If not terminated prior to ninety (90) days, then the Agreement will automatically be extended for an additional year.

The Agreement may be terminated forthwith by either Party for good cause. Any event shall be deemed good cause for immediate termination that would make it unacceptable for the affected Party to continue upholding the Agreement until it can be terminated in the ordinary course of business, in particular:

- If the other Party ceases rendering payment.
- If the other Party continues to be in material breach of the Agreement even after being notified of such breach, and/or fails to remedy the consequences of such breach.

Upon termination of the Agreement, the UK Responsible Person is obligated to send to Manufacturer all information and advertising materials, all other objects that are the property of the Manufacturer, including any other materials concerning the Products that may be in its possession except documents which should be kept as requested by law and the UK Responsible Person shall transfer all registrations including confidentiality aspects and proprietary rights without undue delay.

(11) The Parties consent to execution of this Agreement by means of scanned signature copies in PDF format and that such signatures placed by the Parties on different copies of the signature page(s) shall be deemed to have been executed on one and the same page. The Parties agree not to challenge the validity or enforceability of this Agreement based on either Party's use of such scanned signatures. Delivery of an executed counterpart of a signature page of this Agreement in a non-modifiable electronic copy (e.g., in pdf format) via e-mail is deemed as effective as delivery of an originally executed counterpart of this Agreement.

(12) The Annex 1 to this Agreement constitutes an integral part of this Agreement.

MIPM Mammendorfer Institut für Physik und Medizin GmbH

Jennifer Rosenheimer, Managing Director
Signatory's name & Function

Viamed Ltd.

STEVE NIXON, DIRECTOR
Signatory's name & Function

30/3/21

Annex 1: List of Products

Annex 1

List of Products:

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