

9<sup>th</sup> December 2025

Ref: The UK Responsible Person Agreement ("Agreement") between Sensatronic GmbH, a business unit of Germany ("Manufacturer"), having its principal place of business located at 23970 Wismar, Am Ring 9, Germany, and Viamed Limited ("Viamed"), having its principal place of business as noted below.

## UK RESPONSIBLE PERSON AGREEMENT

We are pleased to confirm Viamed Ltd, United Kingdom as the designated UK Responsible Person (Authorized Representative) of the Manufacturer as described further in Appendix 1, attached hereto and incorporated by reference.

UK offices of Viamed are located at:

Viamed Ltd.  
15 Station Road, Cross Hills, Keighley  
BD20 7DT West Yorkshire  
United Kingdom

Email: [info@viamed.co.uk](mailto:info@viamed.co.uk)  
Phone: +44 (0)1535 634542

If you have any questions regarding this matter, please do not hesitate to contact me

Thank you.

Sincerely,



Jens Schwarz  
General Manager

## Sensatronic GmbH

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Geschäftsführer:  
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Amtsgericht Schwerin  
HRB 7639

Bankverbindungen:  
UniCredit Bank AG, Schwerin  
(BLZ 200 300 00) Kto.-Nr. 19 20 94 94  
Swift code: HYVEDEMM300  
IBAN: DE39 2003 0000 0019 2094 94

Commerzbank AG, Rostock  
(BLZ 130 400 00) Kto.-Nr. 35 18 867  
Swift code: COBADEFF130  
IBAN: DE66 1304 0000 0351 8867 00

## Appendix 1

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 registration obligations laid down in the UK MDR 2002 (SI 2002 No 618, as amended by the UK MDR 2019);
- (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 timelines 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 until 9<sup>th</sup> December, 2030. This Agreement may be terminated by either Party at any upon written notice by written notification to the other Party ninety (90) days prior to the indicated termination date.

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.



## Annex 1

### List of products

Description	Part Number	UDI Number
Reusable rectal/esophageal temperature probe, Adult, phone plug right-angled	011-00119	04260651380197
Reusable rectal/esophageal temperature probe, Adult, Philips connector	011-01401	04260651380401
Reusable rectal/esophageal temperature probe, Pediatric, Philips connector	011-01402	04260651380418
Reusable skin temperature probe, Pediatric, Philips connector	011-01405	04260651380449
Single-use General Purpose temperature probe 9 FR, non-sterile, Molex connector, Philips branding	013-00080	04260651380906
Single-use General Purpose temperature probe 12 FR, non-sterile, Molex connector, Philips branding	013-00081	04260651380913
Single-use Skin temperature probe, non-sterile, Molex connector, Philips branding	013-00082	04260651380920
Single-use General Purpose temperature probe 12 FR, non-sterile, Molex connector	013-00071	04260651381705
Single-use Skin temperature probe, non-sterile, Molex connector	013-00072	04260651381712
Single-use Tympanic temperature probe, non-sterile, Molex connector	013-00073	04260651381729
Single-use General Purpose temperature probe 9 FR, non-sterile, Molex connector	013-00090	04260651380937
Single-use General Purpose temperature probe 12 FR, non-sterile, Molex connector	013-00091	04260651380944
Single-use Skin temperature probe, non-sterile, Molex connector, Philips branding	013-00092	04260651380951
Single-use Tympanic temperature probe, non-sterile, Molex connector	013-00093	04260651380975
Extension cable 3.0 m, Philips connector, Molex connector	013-00162	04260651381392
Extension cable 1.5 m, Philips connector, Molex connector	013-00163	04260651381408
Extension cable 2.0 m, Phone plug right-angled, Molex connector	013-00110	04260651381415