Regulatory Consulting Agreement for:

General Consumer Products

By and between:

Client information:
Vandagraph Ltd.
15 Station Road, Cross Hills, Keighley, BD20 7DT
United Kingdom
(hereafter referred to as "the Client")

and

AF PHARMA SERVICE EUROPE SL
Muntaner 281, 08021, Barcelona, España
(hereafter called to as "AF Pharma")

This Regulatory Agreement (the "Agreement") is entered into between the Manufacturer and AF Pharma Service Europe SL., a company organized under the laws of the Spain and with a principal place of business at Muntaner 281, 08021, Spain. This Agreement takes the place of any prior the Authorised Representative agreements between the parties, which are terminated as of the Effective Date. This Agreement takes effect on the date last executed on the last page.

INTRODUCTION

AF Pharma Service, an established industry leader, has been providing exceptional regulatory support for medical devices, cosmetics, drug products and general products since its inception in August 2013. Our core focus lies in assisting companies in navigating the complex regulatory landscape to develop health products through the most optimal regulatory pathways.

With an unwavering commitment to quality and compliance, we have successfully obtained certifications from renowned regulatory bodies such as the Spanish Health Ministry, MHRA (UK), and US-FDA. These prestigious certifications enable us to serve as Authorised Representative for the EU, UK, and US Agents, empowering us to collaborate with companies across the globe.

Through our comprehensive expertise and extensive network, we have positioned ourselves as a trusted partner in securing grants and funds for our clients. Our association with regulatory authorities allows us to unlock valuable opportunities, ensuring our clients have access to necessary resources to drive innovation and growth.

At AF Pharma Service, we pride ourselves on our deep industry knowledge, meticulous attention to detail, and unwavering dedication to our clients' success. By choosing us as your regulatory support partner, you can confidently navigate the regulatory landscape, accelerate product development, and achieve regulatory compliance while maximizing your business potential.

Our proposal is designed to exceed your expectations. It addresses your needs with innovative solutions, provides a clear roadmap, and offers transparent pricing. We are confident in our ability to deliver outstanding results. Let's discuss further and create a successful partnership.

Maria Agustina Duguine
Founder
AF Pharma

SERVICE PROPOSAL

This Agreement sets forth the terms under which AF Pharma, acting as the Authorised Representative, will represent Vandagraph Ltd. the Manufacturer, for regulatory compliance within the European Union. The Manufacturer produces different devices which fall under the scope of the following EU Directives:

- **2006/42/EC – Machinery Directive**: Governs the design and manufacture of machinery to ensure it meets essential health and safety requirements before being placed on the EU market.
- **2011/65/EU – RoHS Directive (Restriction of Hazardous Substances)**: Restricts the use of certain hazardous substances in electrical and electronic equipment to protect human health and the environment.
- **2014/30/EU – Electromagnetic Compatibility (EMC) Directive**: Ensures that electrical and electronic equipment does not generate or is not affected by electromagnetic disturbance, enabling safe and efficient operation.
- **2014/35/EU – Low Voltage Directive (LVD)**: Applies to electrical equipment within certain voltage limits and ensures that such equipment provides a high level of protection for human health and safety.
- **2014/53/EU – Radio Equipment Directive (RED)**: Regulates radio and telecommunications terminal equipment to ensure safety, electromagnetic compatibility, and the efficient use of the radio spectrum.
- **2014/68/EU – Pressure Equipment Directive (PED)**: Applies to the design, manufacture, and conformity assessment of pressure equipment and assemblies operating above certain pressure thresholds.
- **Regulation (EU) 2023/988 – General Product Safety Regulation (GPSR):** Establishes general safety requirements for consumer products placed on the EU market that are not covered by specific EU harmonisation legislation. The Regulation ensures a high level of protection of consumer health and safety, strengthens risk assessment and traceability obligations, and introduces specific requirements for online marketplaces and products sold via e-commerce.

The Client is established in the United Kingdom and is considered a non-EU economic operator for the purposes of EU harmonisation legislation. AF Pharma acts as EU Authorised Representative where applicable and as EU contact point under Regulation (EU) 2023/988 (GPSR). AF Pharma will act on behalf of the Manufacturer to ensure compliance with the applicable legal requirements, facilitate communication with competent authorities, and maintain the required technical documentation in accordance with the above-mentioned Directives.

Obligations of Manufacturers

The Manufacturer, Vandagraph Ltd., agrees to fulfill the following obligations in accordance with the applicable EU Directives listed in this Agreement:

1. **Product Compliance**
   Ensure that all products placed on the EU market comply with the essential health, safety, and environmental protection requirements established under:
   - Directive 2006/42/EC (Machinery)
   - Directive 2011/65/EU (RoHS)
   - Directive 2014/30/EU (EMC)
   - Directive 2014/35/EU (Low Voltage)
   - Directive 2014/53/EU (Radio Equipment)
   - Directive 2014/68/EU (Pressure Equipment)
   - Regulation (EU) 2023/988 – General Product Safety Regulation (GPSR):
2. **Technical Documentation**

   Where is applicable, to prepare and maintain up-to-date technical documentation demonstrating product conformity with applicable EU requirements. This documentation shall be compiled in accordance with the directives and made available to the Authorised Representative upon request.
3. **EU Declaration of Conformity**

   Draft, sign, and provide an EU Declaration of Conformity for each product model placed on the market, ensuring that the declaration references the correct directives and harmonised standards. The EU Declaration of Conformity shall be drawn up and signed by the Manufacturer. AF Pharma may assist in its preparation upon request.
4. **CE Marking**

   Affix the CE marking to only compliant products as per CE regulations. AF Pharma will advice you with no charge for the time consumed.
5. **Provision of Information**

   Provide the Authorised Representative with all necessary documentation, declarations, test reports, risk assessments, and any other relevant information required for demonstrating compliance and for responding to inquiries from EU market surveillance authorities. This should be requested if applicable and from the Authorities requests.
6. **Prompt Notification**

   Inform the Authorised Representative without delay of:
   - Any product non-compliance or safety issues

- Incidents or complaints received from EU customers or authorities
- Any recalls, withdrawals, or corrective actions related to the products in the EU market

7. **Cooperation with Authorities**

   Cooperate with competent authorities in the EU in response to any request for information, corrective action, or investigation concerning the conformity of the products.

8. **Product Identification and Traceability**

   Ensure that products are labelled with the necessary identification, including type, batch or serial number, and the name and address of the Manufacturer and the Authorised Representative (AF Pharma).

9. **Maintain Records**

   Retain the technical documentation and the EU Declaration of Conformity for a minimum of 10 years after the product has been placed on the EU market or for the duration required by each applicable Directive.

Obligations of authorised representatives

AF Pharma, acting as the Authorised Representative of Vandagraph Ltd., agrees to fulfill the following responsibilities in accordance with the applicable European Union legislation:

1. **Representation Within the EU**
   Act as the Manufacturer's official point of contact within the European Union for the purposes of communication with competent authorities and market surveillance bodies regarding the products covered by this Agreement.

2. **Verification of Compliance Documentation**
   Verify that the Manufacturer has drawn up the required EU Declaration of Conformity and technical documentation before placing products on the EU market.

3. **Availability of Technical Documentation**
   Maintain a copy of the technical documentation and EU Declaration of Conformity at the registered address for inspection by competent EU authorities, for a period of 10 years after the product has been placed on the market, or as otherwise required under the applicable Directive.

4. **Cooperation with Authorities**
   Upon reasoned request by a competent authority, provide access to the technical documentation and all relevant information demonstrating product conformity, and cooperate with the authority in any preventive or corrective action taken to eliminate the risks posed by the product.

5. **Incident Reporting**
   Inform the Manufacturer of any complaints, incidents, or requests received from EU authorities concerning product safety, conformity, or corrective actions, and assist in responding to such matters in a timely and coordinated manner.

6. **Product Identification**
   Ensure that the Manufacturer includes the Authorised Representative's name and address on product labelling, packaging, or accompanying documentation, as required by applicable legislation.

7. **Withdrawal and Recall Assistance**
   Support and coordinate with the Manufacturer in executing product withdrawals, recalls, or other corrective measures in the EU market when necessary to ensure compliance and product safety.

8. **Regulatory Updates**
   Inform the Manufacturer of significant changes in the applicable EU legislation, standards, or regulatory expectations that may impact the compliance of their products.

9. **Record-Keeping**
   Keep records of all products covered under this Agreement, including copies of declarations and certificates, and ensure traceability in the event of an audit or inspection by competent authorities.

10. **Confidentiality**
    Maintain strict confidentiality regarding all technical, commercial, and regulatory information received from the Manufacturer, except when disclosure is required to comply with legal obligations under EU law.

AF Pharma does not assume the role of manufacturer, importer, or distributor, and does not assume responsibility for product design, testing, or conformity assessment.

FEES STRUCTURE:

This section sets out the fees and commercial terms applicable to the Authorised Representative services provided by AF Pharma to Vandagraph Ltd. The fees correspond to the scope of services and responsibilities defined in this Agreement and are intended to cover the activities necessary to support compliance with the applicable European Union regulatory framework. Unless otherwise expressly stated, all fees are quoted in Euros and are exclusive of any applicable taxes, duties, or governmental charges.

Service	Price
EU Authorised Representative (including Responsible/Designated Person)	€500/year

Currently there are no EU organizations fees, if this changes, we will let the manufacturer know.

GENERAL PROVISIONS

1.1. Limitations

The Manufacturer bears sole responsibility for the testing, verification, safety, performance, and conformity of its Products, including any required calibration, installation, maintenance, servicing, or repair activities.
AF Pharma is not appointed, nor shall this Agreement be interpreted as appointing AF Pharma, as a manufacturer, importer, distributor, or as any person responsible for placing products on the market or putting them into circulation, as such terms may be defined or interpreted under applicable laws or regulations.
AF Pharma assumes no responsibility and expressly disclaims any liability, whether contractual, statutory, or otherwise, for the safety, efficacy, fitness for purpose, suitability, marketability, regulatory compliance, or performance of the Products, or for the acts or omissions of any third parties, other than AF Pharma's own personnel.
To the extent that any applicable law or regulation imposes or is interpreted as imposing any liability on AF Pharma in connection with the Products, the Parties expressly agree that such liability shall be borne by the Manufacturer in accordance with the indemnification provisions of this Agreement.

1.2. Compliance

The Manufacturer shall take all appropriate measures to ensure full compliance with all responsibilities, liabilities, and obligations imposed by applicable laws, regulations, and rules ("Applicable Rules") governing the Products. Such obligations include, without limitation:
(i) traceability of the Products to the Manufacturer and, where required, to AF Pharma;
(ii) reasonable traceability of the Products to end users;
(iii) compliance with all applicable labelling, marking, and information requirements;
(iv) compliance with applicable language requirements;
(v) compliance with applicable marketing, advertising, and claims requirements; and
(vi) any additional obligations arising from the specific characteristics or intended use of a Product.

Upon the Manufacturer's request, and subject to the Supplemental Support provisions of this Agreement, AF Pharma may provide regulatory guidance or advice regarding compliance matters. Any standard document review support included within the scope of this Agreement shall be provided without additional charge.
Upon request by AF Pharma, the Manufacturer shall promptly provide all documentation reasonably necessary to demonstrate compliance of the Products with the Applicable Rules.
The Manufacturer shall promptly notify its importers, distributors, and AF Pharma upon becoming aware, or having reasonable grounds to believe, that any Product is not in conformity with the Applicable Rules. The Manufacturer shall also provide AF Pharma with timely information regarding any planned or ongoing corrective actions, withdrawals, or recalls necessary to restore or ensure compliance.
Where a Product presents a serious risk, the Manufacturer shall immediately inform the competent authorities of the Member States in which the Product has been made available, and any notified body involved, where applicable, in accordance with the Applicable Rules.
AF Pharma shall inform the Manufacturer of any request received from a competent authority for Product samples. Upon such request, the Manufacturer shall provide the requested Product samples directly to the authority or, where this is impracticable, grant the authority access to the Product. AF Pharma shall request confirmation from the authority that such samples or access have been received.

The Manufacturer shall not advertise, market, or place Products on the EU market using any false, misleading, or non-compliant information or claims, or any claims not supported by and included in the Product technical documentation.
The Manufacturer shall provide AF Pharma with prior written notice of any material changes to a Product, its technical documentation, or any information demonstrating compliance with the Applicable Rules. This includes, without limitation, any changes to Product labelling, packaging, instructions for use, marketing materials, or claims. Subject to the Supplemental Support provisions of this Agreement, AF Pharma may assist the Manufacturer in assessing whether such changes may affect the regulatory status or compliance of a Product.
Where a Product is subject to a notified body-issued CE certificate, the Manufacturer shall immediately notify AF Pharma if such certificate is suspended, restricted, modified, cancelled, or withdrawn. In such circumstances, the Manufacturer shall ensure that the affected Product is not made available on the market until the issue has been resolved and, where applicable, a valid CE certificate has been reinstated. The Manufacturer shall ensure that its importers and distributors comply with this obligation.
If a competent authority initiates any investigation, enforcement action, penalty, or administrative or legal procedure against the Manufacturer arising from non-compliance with the Applicable Rules by the Manufacturer or its importers or distributors, the Manufacturer shall remain solely responsible for such non-compliance. Where such action is taken directly against AF Pharma or its personnel as a consequence of the Manufacturer's non-compliance, the indemnification provisions of this Agreement shall apply.
By entering into this Agreement, the Manufacturer represents and warrants that, as of the effective date, the Products covered by this Agreement are in compliance with all applicable EU regulatory requirements, and acknowledges that it remains solely responsible for maintaining such compliance at all times.

1.3. Vigilance and Product Safety Monitoring

AF Pharma shall promptly inform the Manufacturer of any complaints, inquiries, or information relating to product safety, incidents, or risks concerning any Product that it receives from authorities, consumers, or other third parties. This obligation shall survive termination of this Agreement for as long as AF Pharma is identified on Product labelling or documentation, or for any longer period required under applicable laws or regulations.
Where the Manufacturer becomes aware of any product-related incident, safety issue, or potentially reportable event (each an "Incident") affecting a Product, the Manufacturer shall immediately provide AF Pharma with all relevant information reasonably available, including any information required under applicable product safety legislation, including Regulation (EU) 2023/988 (GPSR). This obligation shall survive termination of this Agreement for the same duration as set out above.
The Manufacturer shall promptly inform AF Pharma of any corrective or safety-related actions undertaken in any country outside the European Union in relation to a Product, where the reason for such action is not strictly limited to that specific market and may have relevance for products placed on the EU market.
The Manufacturer shall be solely responsible for analysing product complaints, safety signals, incidents, and other post-market information relating to the Products. Upon request, the Manufacturer shall provide AF Pharma with a summary of its assessment and any conclusions reached. Where preventive or corrective actions are required, the Manufacturer shall implement such measures without delay and, where applicable, inform the relevant competent authorities in accordance with applicable laws.

AF Pharma may, upon the Manufacturer's request, provide non-binding regulatory guidance regarding product safety obligations, risk assessments, incident reportability, and corrective actions under applicable product safety legislation.
Where applicable laws require periodic product safety reporting or documentation, the Manufacturer shall prepare such reports and provide a copy to AF Pharma upon request.
AF Pharma shall comply with any lawful instruction received from a competent authority in relation to the Products and shall inform the Manufacturer of any such instruction without undue delay. Where appropriate, and upon the Manufacturer's request, AF Pharma may communicate the Manufacturer's position to the competent authority.
Upon reasonable request, the Manufacturer shall provide AF Pharma with an annual written confirmation stating whether any reportable Incidents occurred during the preceding year. This obligation shall survive termination of this Agreement for as long as AF Pharma is identified on Product labelling or documentation, or as otherwise required by applicable law.
AF Pharma shall not be responsible for the accuracy, completeness, or correctness of information provided by the Manufacturer, nor for any incorrect interpretation of such information. Any liability, costs, or damages incurred by AF Pharma arising from inaccurate, incomplete, or misleading information provided by the Manufacturer shall be borne solely by the Manufacturer and handled in accordance with the indemnification provisions of this Agreement.

1.4. Confidential Information

AF Pharma shall treat as strictly confidential all non-public, proprietary, commercial, technical, or regulatory information received from the Manufacturer in connection with this Agreement ("Confidential Information"). AF Pharma shall not disclose such Confidential Information to any third party or use it for any purpose other than the performance of the Services under this Agreement.
Notwithstanding the foregoing, AF Pharma may disclose Confidential Information to competent authorities, regulatory bodies, or other governmental entities solely to the extent required by applicable laws or regulations, or as necessary to carry out its obligations under this Agreement.
This confidentiality obligation shall survive the termination or expiry of this Agreement for as long as the Confidential Information remains confidential or for any longer period required by applicable law.

1.5. Proprietary Information

All intellectual property rights, whether registered or unregistered, and whether registrable or not, including without limitation any designs, formulations, documentation, technical data, trademarks, copyrights, know-how, and any developments or improvements relating to the Products, shall remain the sole and exclusive property of the Manufacturer.
Nothing in this Agreement shall be construed as granting AF Pharma any ownership rights, license, or other interest in the Manufacturer's intellectual property, except to the limited extent necessary for AF Pharma to perform the Services under this Agreement.
This section shall survive the termination or expiry of this Agreement

1.6. Termination

Either Party may terminate this Agreement upon written notice to the other Party in the event of a material breach of this Agreement by the other Party that is not cured within thirty (30) calendar days of receipt of written notice specifying the breach.

Either Party may also terminate this Agreement for convenience at the end of the applicable contract term by providing written notice prior to the renewal date, in accordance with the terms of this Agreement.
Termination or expiry of this Agreement shall not affect any rights or obligations which by their nature are intended to survive termination, including without limitation obligations relating to confidentiality, liability, indemnification, product safety, and regulatory cooperation.

2. INFORMATION FOR THE CLIENT

Information to be added in the label:

AF SERVICE EUROPE SL
Muntaner 281, 08021, Barcelona, España
info@afpharmaservice.com

In witness whereof, this Authorised representative Agreement is entered into as of the date written last below:

Client
Vandagraph Ltd.

Signature:
Name: RYAN SWAINE
Title: GENERAL MANAGER
Date of signature: 20/01/2026

AF Pharma

Signature:
Name: Maria Agustina Duguine
Title: President
Date of signature: 20/02/2026

AF PHARMA SERVICE EUROPE S.L.
CIF: B67780684
European Union