

Contract

for the purpose of defining the scope of responsibility for compliance with legal requirements of medical products and quality assurance between the

Buyer:

**Vandagraph Sensor Technologies Ltd.
15 Station Road, Cross Hills, Keighley,
West Yorkshire BD20 7DT
United Kingdom**

(hereinafter referred to as Buyer) and the

Manufacturer:

**EnviteC-Wismar GmbH –by Honeywell-
Alter Holzhafen 18
23966 Wismar, Germany**

(hereinafter referred to as Manufacturer).

0. Preamble

The products manufactured by Manufacturer (including, for example, materials, packaging, instruction for use and labelling) shall be marketed by Buyer on Buyer's own responsibility and in Buyer's own name.

1. Term and termination of the agreement

The agreement shall come into effect as of 01.08.2010 and shall be valid for an indefinite period; it may be terminated by either party by giving six months' notice prior to the end of the month. The agreement shall be terminated by registered letter.

This contract terminates automatically without further notice on the effective date of any termination or expiry of the sales agreement for the products manufactured by the Manufacturer.

In case of termination of expiry or succession or novation all relevant information to guarantee, in particular, the duty to observe and report shall be handed over to the other party.

The obligation to keep documentation and records in accordance with sections 3 to 5 of the agreement shall remain in force for a period of ten years after the last product has been sold.

*pp. S. Brighi
pp. S. Kichas*

2. Products

Product name	Product identification Manufacturer	Product identification Buyer
• OOD103	1001570	REF 8010000 / VST2200
• OOD103	1001570	REF 8010001 / APD 5
• OOD103-1	1001580	REF 8010003 / VR1700
• OOD103-1V	1001581	REF 8010002 APD 11

Products are specified as agreed with Buyer according the attachment: Document No.: 001-05-
OOD10300-B, 06/2010

3. Obligations of Manufacturer

Manufacturer undertakes to meet the basic requirements of the legal provisions pursuant to section 2. This obligation enables Buyer to refer to the manufacture, quality assurance and final inspection of Manufacturer for which Manufacturer is responsible.

Manufacturer shall maintain a reasonable amount of information that allows traceability of the product for Buyer (based on the serial number/batch).

In order to market the above-mentioned products, the following information shall be made available to Buyer:

☐ General description, variants (specifications)

Manufacturer shall furnish Buyer with information about all substantial changes in the manufacturing process, in the case of product modifications and changes in the materials used for the products that have an impact on product quality and safety.

If any material changes arise in the course of the certification of the products or Manufacturer, Buyer shall be informed as soon as reasonably possible.

4. Requirements of the quality assurance system and of certification

Buyer shall, in the case of use of Buyer's own label (private label), assume the liability of the manufacturer pursuant to statutory provisions.

M. S. Brigt
M. Schröder

5. Quality audits

Notified bodies and authorities of Buyer are entitled at any time after prior arrangement of an appointment during normal office hours to conduct quality audits at Manufacturer's premises.

In special cases (e.g. complaints or complaints in accordance with section 7), Buyer shall be permitted to inspect the QM system after consultation with Manufacturer.

6. Obligations of Buyer

Buyer shall maintain and make available technical documentation on the products in section 2, any accompanying information and safety instructions, as well as the declaration of conformity.

Buyer undertakes to set up a system for batch traceability.

7. Reporting of incidents/product observation/corrective action

Both parties to the agreement shall inform each other as soon as reasonably possible of all product risks/malfunctions regarding the aforementioned products that become known to them. This shall also apply to products or comparable products which have resulted or could have resulted in the death or a serious deterioration in the health of a patient or user or in a product call-back.

8. Duty to notify and report

Each party shall be individually responsible for performing the national duties to observe, notify and report incumbent upon them in their functions as Buyer and Manufacturer.

9. Final provision

Manufacturer excludes all liability for all damages whatsoever and howsoever caused other than for intentional or grossly negligent actions. In case of a breach of a material obligation Manufacturer will be liable for its negligence but only to the extent of the contractually typical and foreseeable damages. Claims for loss of profit, savings, claims of third parties as well as other indirect and consequential damages are excluded. Manufacturer does not seek to exclude or restrict its liability for: death or personal injury, fraud, specific quality guarantees or claims pursuant to the Product Liability Act.

Manufacturer has not been informed about the application of the products. Buyer accepts full liability for the application and sale of the products. Manufacturer only provides its standard product warranty in accordance with its general terms and conditions to Buyer. Buyer indemnifies Manufacturer against any and all claims, damages and losses in connection with its application and its sale of the products.

This agreement is subject to German law and the parties submit to the exclusive jurisdiction of the courts in Schwerin. Any amendments to this agreement shall be made in writing. This agreement is not transferable to third parties, which are not affiliated companies in the sense of §§ 15 Aktiengesetz, without the consent of the parties to the agreement. The obligations arising from this agreement will pass to the legal successor. .. If any provision of this agreement or part of a provision is determined by a court of competent jurisdiction to be illegal, invalid, or unenforceable, for any reason, then such provision or part or a provision shall be deemed stricken out for the purpose of the dispute in question, but only to the extent necessary to make the remaining portion of the provision legal, valid and enforceable, if possible, and all other provisions of this agreement shall remain in full force and effect.

ppa. S. Brige
ppa. S. Brücke

Buyer

Place/date

.....
Stamp / signature

Manufacturer

Place/date *Lisbon, 5.08.2010*

pe. Stokun
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Stamp / signature