New Medical Equipment or Product Information Form

For completion by Supplier/Representative to enable informed discussion at GOSH Medical Equipment & Supplies Group (MESG)

(Please ensure completion of all sections)

Device Name - VersaStream Oridion CO2 Airway Adapter - Infant (ID < 4.0mm) – Long-Term (High Humidity)	**Supplier – Viamed Ltd.**	**GOSH Contact details -**

	PRODUCT OVERVIEW	
1.	Product Details Please include • Relevant function, product codes and/sizes • Product brochure • Instructions for Use document/manual (IFU) • Specific storage instructions if required • Manufactures intended purpose for use.	**Part Number:** 4420926 **Description:** VersaStream Oridion CO2 Airway Adapter Sampling Line Infant (ID < 4.0mm), Long-term (high humidity) Box of 25. **Product Brochure and IFU attached.**
2.	Details of manufacturer and supplier/distributor Is this a new supplier to GOSH?	**Manufacturer:** Bluepoint Medical GmbH **Supplier/Distributor:** Viamed Ltd. **Existing Supplier**
3.	Does the device/product contain latex? • Console / equipment / probe etc? • Consumables? • If latex present, is a latex free alternative available?	No latex Consumable
4.	Does the device/product contain any elements which are known to cause allergies? • For example, but not limited to – • Gluten, Peanut, Egg or Dairy, Animal by-products, Human Cells or Tissue, Shellfish or Fish by-products • If yes, please provide details	No
5.	Is the device/product single use or reusable? • If reusable, please provide documentation regarding cleaning &/or sterilisation instructions as appropriate. • Please ensure to include cleaning instructions for all elements (including console). • Confirmation if the following products suitable for use? Clinell Universal Wipes, Clinell Clorox, Chlor-clean.	Single Use
6.	Are there consumables or other requirements needed for the product/equipment? • If yes, please provide details of consumables required including cost, range etc. • Specific storage requirements etc?	Item is a consumable Single Use Sampling Line
7.	Are there any additional instruments or other items required for use? • If yes, please provide details of instrumentation required including cost, range etc.	Main device not supplied by Viamed
8.	Is the product/equipment CE or UKCA marked? If yes, please provide details noting changes to Government Regulation requirements. If no, please provide details as to why this is not required.	Yes – CE, certificate attached.
9.	Is the product/device registered as a medical device? Please provide details of Directive as appropriate.	Yes - MDD

10.	How long has the product been available for sale within the UK market?	2018
11.	Is the product/equipment licenced for use in Paediatrics?	Yes
12.	Is the product/equipment used within other Paediatric trusts in the UK? Please provide details if possible	University Hospital of Wales
13.	Will the product/device be used in the community? If yes, please provide details as appropriate.	It can be, we supply VersaStream to customers for use on compatible devices, if those devices are then sent out by the NHS for use in the community, then the VersaStream accessories would accompany those devices.
14.	Details of any known adverse events/outcomes and risks associated with the product/equipment. Include details of any contraindications.	To avoid damage to the skin of the nose, do not exceed the maximal O2 flow rate of 5 l/min. There are no known contraindications for patient monitoring with the sampling lines provided that the data obtained by the gas monitoring is evaluated with consideration given to the patient's clinical condition.
15.	Are there any published clinical papers to support the product/equipment? (please provide copy of documents)	Requested from manufacturer.
INFORMATION GOVERNANCE & ICT		
16.	Does the device have the ability to capture images and/or patient data? • Is the device Wifi compatible? • If yes, is the device compatible with EPIC (electronic patient data system)? • How will the data be downloaded & stored?	No
17.	If yes, please provide details of the following – Details of data set that will be processed through Cardiovit	
18.	Will there be any personal data and/or pseudonymised data and/or anonymised data?	No
19.	Will any data processing (including access, transfer and storage) occur outside the UK?	No
20.	Details of data flow, i.e. what data will go where/be accessible by whom (including 3rd parties and sub-processors)	n/a
21.	Is it intended that data gathered will be shared with the supplier/manufacturer? If yes, please detail how this data will be used	n/a
22.	Confirmation there are no ongoing costs for software or licensing.	n/a
USE OF THE PRODUCT AT GOSH		
23.	What will be the use/requirement of the product at GOSH? (eg. Specific conditions or situations) Is this a new procedure to GOSH?	
24.	What areas will use the product/equipment? (this is to ensure standardisation where possible across the trust)	
25.	Will this require new surgical techniques or other?	
26.	Are there any specific post-op/post-use cares required for the patient?	
27.	What are the benefits for GOSH of using the	

	product/equipment?	
28.	Will any other teams require consultation & communication? E.g. Estates & facilities, TVN, Manual Handling, Resus etc e.g. If equipment, • Consider size of equipment • Weight of equipment • Location where equipment will be used, can the floor support the weight? • If equipment will be moved around the Trust, will it fit into the lifts? Are the doors wide enough?	
COSTINGS & SUPPLY OPTIONS		
29.	What is the cost of the product/equipment? (inc. or ex. VAT) Please include costing details of console & consumables as appropriate Please include details of spare parts as appropriate.	£340.00 ex VAT per box of 25 lines.
30.	Details of delivery options and costs	£12.00
31.	What is the lead time for products/equipment?	1-3 working days
32.	What is the route of supply for the product/equipment?	Germany – UK
33.	Is the product/equipment available via a framework?	No
34.	Is there an option for consignment or sale/return of consumables/implants/instruments?	No
MAINTENANCE & DISPOSAL		
35.	What is the lifespan of the product/equipment?	Single Use, <72 hours
36.	Please provide details of how the product/equipment is powered? Please include details of battery life, recharging, securement of battery cover etc as appropriate.	n/a
37.	Details of appropriate disposal route. What is the environmental impact of equipment disposal?	See Viamed General Disposal Instructions. Disposal through the Trusts contaminated waste management procedures.
38.	Are there servicing or maintenance costs associated with maintaining the product/equipment?	n/a
39.	Can GOSH Biomedical Engineering be trained to undertake any maintenance, service or repairs?	n/a
ENVIRONMENTAL IMPACT & SUSTAINABILITY		
40.	Details of Environmental impact during manufacture and product use	Please see our Policies Page: https://www.viamed.online/pages/policies
41.	Details of Environmental impact of disposal of consumables	Please see our Policies Page: https://www.viamed.online/pages/policies
42.	How is the manufacturer/supplier working to be an Environmentally sustainable partner?	Please see our Policies Page: https://www.viamed.online/pages/policies
EVALUATION AND TRAINING		
43.	Is the supplier willing to support the evaluation with FOC products/loan? Please provide details of time period and items included in evaluation.	n/a Disposable consumable.
44.	What are the training requirements associated with product/equipment? Including – • New surgical techniques? • Device use? • Post-op cares?	n/a Direct compatible to existing OEM sampling lines.
45.	What groups of staff need to be trained for this	n/a Direct compatible to existing OEM

	product/equipment? • Consider - if equipment, will it be moved? • E.g. Does it require manual handling input and education?	sampling lines.
46.	Is the supplier able to supply education & training along with materials if required?	No
47.	Is the supplier able to provide specialist support on site if required during evaluation? • Please Note – GOSH require registration via www.miaweb.co.uk prior to site visit. • Standards of professional code of conduct are expected to be maintained if visiting GOSH premises.	No
48.	Is an evaluation form available? If so, please attach	n/a
49.	How many patients are proposed to be included in the evaluation?	n/a
50.	What is the proposed time frame of the evaluation period?	n/a
	OTHER	
51.	Declare any details of conflict of interest	n/a
52.	Declare any details of Gifts, Hospitality or Sponsorship provided	n/a
53.	Declare any Ethical issues for the Trust or wider community	n/a

Completed by

Signature: C Hollings Print Name: Catrin Hollings Date: 28/02/24

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