VIMAP TECHNOLOGIES

Date: 14 of April 2020

VMW-1020A CO2 insufflator & Coronavirus COVID19. Cleaning aspect, cross-contamination risk and room contamination risk

Scope of VMX-1020A: Colon & small intestine Insufflator for virtual colonoscopy, virtual enteroscopy and intussusception reduction.
Specifies name: VMX-1020A
Brand/model: VIMAP Technologies
Manufacturer: VIMAP Technologies
Country of origin: Spain
Manufacturing site: Paseo de la Hispanidad N°1 y 2, Polígono Industrial, 29130 Alhaurín de la Torre, Málaga, Spain
Risk- based classification: Class B
Classification rule: Rule 11
GMDN code: 36747
HS code: 90189084
Medical device registration number of any approval code: HD60110955 (TUV Rheinland)

Cleaning aspect of the device:

The instructions issued by the sterilization managers of each hospital or medical center must be followed in all cases.
These instructions will take precedence over the information contained in the present manual which is provided for guidance only.
Always unplug the device from the power outlet before cleaning.

After each use:
Discard the disposable tubing - do not attempt to sterilize it.
Clean up any splashes of liquid present on the device by wiping with a damp cloth.
The unit must be decontaminated before sending it to the after-sales service.

Cross contamination risk:

References of VIMAP Technologies single use administration sets available for VMX-1020A:
AS-3W-H-R35A (virtual colonoscopy or CTC)
AS-3W-H-R35B (intsussusception reduction)
AS-SI-H-R35A (virtual enterosocpy or virtual enteroclysis)

Direction of the flow patient to machine: Before reaching any internal components of the machine or being vented in the room during the release of over pressures, the CO2 is going through 2 filters (see annex 2): a first filter and then a second filter located at 40cm from the first one.

Direction of the flow machine to patient: Before reaching the patient, CO2 is going through the 2 filters of the administration sets.

VIMAP administration sets for VMX-1020A (see annex 2) are using specific high-performance filters GVS ref 2000/05 that are anti-bacteria, anti-viral and hydrophobic. Protection against virus is average of 99.9995% with minimum at 99.9973% (see GVS 2000/05 properties in annex 1). **The filter barrier is not one but two consecutive filters**.

The administration set is single use consumable and is changed at any patient, before every new exam. Due to this **double barrier**, the probability of cross-contamination between 2 patients is neglectable even in the very unlikely case of contamination of the internal device components.

Note: The VMX-1020A is the only CO2 insufflator using single use administration sets with a redundant filter barrier including 2 filters. In the eventuality of any contamination of first filter by direct contaminated liquids that would enter in contact with the filter and affect its filtration properties, the second filter in this situation would remain fully efficient and clean. The hydrophilic property of the first filters would prevent the second filter from any risk of contact by contaminated liquids.

Room air contamination risk by release in the room of intra colonic contaminated CO2

VMX-1020A is releasing the pressure after the end of the exam electronically and automatically. An insufflated patient colon contains in average 1,5l of potentially contaminated CO2. With VMW-1020A, this quantity is filtered before being releasing in the room: There is no risk of contamination of the room by this quantity of contaminated CO2.

Technical explanation: When you stop the machine at the end of the exam, machine will open the release valves that are opened by default. We have 2 electronic valves for release of over pressures + 2 mechanical safety valves (only used in case of abnormal over pressure in case of electronic failure). One electronic valve is proportional for adjusting small over pressures and the second electronic valve is open/closes for large over pressure. Booth of them are **naturally opened,** means that when machine is off (power cut), or when you end the exam, they are booth fully opened.

This is the warranty that all quantity of CO2 present in the colon after insufflation will be going out of the patient colon after the stop/end of the exam will go through the administration set filters before being released in the CT room.

Conclusion:

VMX-1020A cross-contamination and room contamination risk **is neglectable** and near zero due to the safe design of the device and due to anti-viral property of the 2 redundant high-performance filters used in each the administration sets:

Authorized Signatory:

Nicolas Costovici

Position: CEO

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ANNEX
1

GVS FILTER TECHNOLOGY

PRODUCT SPECIFICATION

Product PN 2000/05

Mod. 984

Rev. 02

Description 2000/05 Vent Filter – Glass Microfibre Media

2000/05 – Vent Filter

PRODUCT DESCRIPTION	2000/05 - Vent filter, 8mm HB, HOMO PP/Green Ring, GMF media
MANUFACTURER NAME	**GVS Filter Technology UK** NFC House Vickers Industrial Estate Mellishaw Lane, Morecambe Lancashire LA3 3EN - United Kingdom **Information** Tel. +44 (0) 1524 847600 Fax: +44 (0) 1524 847800 e-mail: gvsuk@gvs.com
INTENDED USE / APPLICATION	Hydrophobic filter medium prevents the backflow of body fluids and blood, stopping cross-contamination and damage of the insufflation apparatus
CLASS OF THE PRODUCT	Disposable medical device - Class IIa Rule 2 Annex IX 93/42 / EEC
MATERIALS	**Filter media:** Hydrophobic Glass Microfibre Media **Frame/Housing Polymer:** Polypropylene material **Color:** Transparent with green Overmould ring

PRODUCT CHARACTERISTIC	**Physical/Mechanical:** **Dimensions:** 54.0mm Diameter **Weight:** 11.6gm (approx.) **Effective Filtration Area:** 17.0cm² **Interfaces (ex: Input/Output connectors):** 8mm-8mm hose barbed connector **Operating temperature Range:** From +5°C to 40°C **Storage temperature Range:** From 0°C to 55°C **Biological:** **Pyrogenicity in accordance with GVS Procedure IC-656:** <0.25 Eu/ml **Sterilisation:** Ethylene Oxide (Max 55°C)

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PRODUCT CHARACTERISTIC	**Functional:** **Air Flow Rate:** at 5PSI: 106l/min – Minimum **Burst Pressure:** 80 PSI **Static Head Test:** 27" water for 1 minute Filtration Efficiency (DEHS @ 0.3µm @ 30l/min flow rate: 99.997% - Average (Minimum - 99.995%) **Bacterial Filtration Efficiency in accordance with ASTM F2101-07:** (Staphylococcus aureus @ 30L /minute): Average – 99.999993% (Minimum – 99.999993%) **Viral Filtration Efficiency in accordance with ASTM F2101-07:** (Bacteriophage @ 30L/ minute): Average – 99.9995% (Minimum – 99.9973%)
INSTRUCTIONS **WARNINGS**	**Precautions:** For Your Safety and that of Your Patients. Follow the Instruction for Use of the basic machine. • To avoid contamination and soiling, the product should remain packaged until ready to be used. • Replace the filter if increase in resistance occurs. Following use, the products must be disposed of in accordance with the local hospital, hygiene and waste • Disposal regulations. **WARNING: The statements below provide important information about a potentially hazardous situation which, if not avoided, could result in injury to the patient.** • Any use of the medical device requires full understanding and strict observation of all portions of these Instructions for Use. The medical device may only be used for the purpose specified under "Intended Use". Observe all WARNING statements throughout this manual and all statements on medical device labels. The manufacturer disclaims any liability for patient injury caused by noncompliance with these statements. • Before installation, check that all system components are free of obstructions and of foreign bodies. Otherwise, use is limited, or faulty operation is possible. • Do not use the product if the packaging is damaged. • Do not use if product appears damaged
PRODUCT SHELF LIFE	5 years from the date of manufacture. Expiration date and date of manufacture are detailed on the product
STERILIZATION	Ethylene oxide (Max 55°C)
APPLICABLE STANDARDS AND REGULATIONS	Biological evaluation of Medical Devices. Part 1 Evaluation and Testing: ISO 10993-1 Sterilization of health care products - Ethylene Oxide sterilisation: ISO 11135-1 Sterilisation of medical devices – Microbiological Methods – Part 1: Estimation of population of Microorganisms on products: ISO 11737-1 Respiratory protective devices - Method for test - Part 7: Determination of particle filter penetration: BS EN 13274-7

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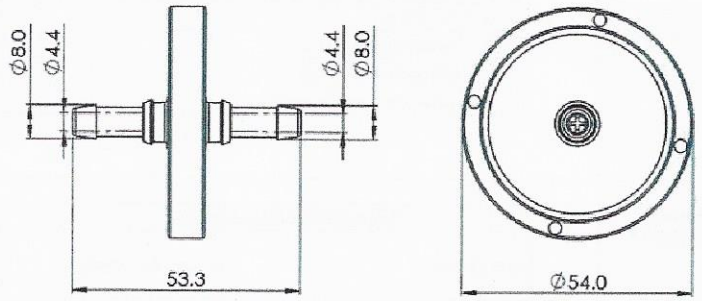
	Medical devices- Application of risk management To medical devices — BS EN ISO 14971 Medical devices – symbols to be used with medical Device labels, labelling and information to be supplied Part1: General requirements — ISO 15223-1
BIOLOGICAL REQUIREMENTS	Test performed in compliance with USP class VI and/or ISO 10993-1. Finished product test.
PACKAGING AND LABELLING	Number of pcs per bag is determined by the Sales order. The first bar-code label is outside the bags. The second bar-code label is stuck outside the box. Each bag is labelled with the following traceability information: ✓ Quantity ✓ Product Description ✓ Product Date ✓ Lot Number (OL and 5 digit batch number to trace back to raw materials used) ✓ Operator Code Different lots in one box are separately closed and separately labelled. Bulk products will be packaged in double PE bags.
CERTIFICATE OF	The Quality Management system is in compliance with ISO 9001 and ISO 13485
DRAWING	

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VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under the conditions below:

Magnification: Unaided eye at a distance of approximately 35-40cm.
Illumination: Lighting level must be reasonable for visual detection i.e. 1000Lux
Timings: Maximum inspection period per item 25s

	Acceptance Requirement	AQL	Sampling Plan
1	Black particle contamination - loose (≥0.2mm2)	0.65	ISO 2859 Part 1 Inspection Level 1
2	Surface damage	0.65	
3	Blocked connector / luer	0.65	
4	Weld marks	0.65	
5	Short fill moulding (functional)	0.65	
6	Short fill moulding (non functional)	0.65	
7	Rough surface or edges	0.65	
8	Pronounced injection gate	0.65	
9	Bubble in moulding (max 3 air bubbles)	0.65	
10	Deformation / Distortion	0.65	
11	Crack	0.65	
13	Wrong colour	0.65	
14	Flash	0.65	
15	Weld fault	0.65	
16	Oil / grease	0.65	
17	Flow marks / marbling	0.65	
18	Wrong artwork / printing	0.65	
19	Incomplete or missing membrane	0.65	

PERFORMANCE REQUIREMENTS

	Acceptance Requirement		AQL	Sampling Plan
1	Static Head Test	27" water for 1 minute	0.65	ISO 2859 Part 1 Special Inspection Level 3

This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

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REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
04/12/15 03/11/2016	0 1	Initial Release Updated to Rev. 02 and Specification updated with Minimum and average values added	Rob Davis-Lead Engineer Ben Rowan – Project Design Engineer B Rowan	Rebecca Law- QA

Customer Approval:

We accept this material specification as a part of the agreed terms of delivery

Company name _____

Approved by: _____

(Name, Function) (Signature)

Date _____

_____

(Company stamp)

Please send back this document signed for approval. If we will not receive this specification signed , we consider the first order placed as implicit approval.

ANNEX

2

VIMAP TECHNOLOGIES	Num.:		Date (YYYY-MM-DD):	2020-04-14
	Title:	2020-04-14- GVS filter- H refs	Version:	1.0