

GVS Filter Technology UK – Legal Manufacturer  
Medical Air Filtration Division  
NFC House  
Vickers Industrial Estate  
Mellishaw Lane  
LA3 3EN

Tel: +44 (0) 1524 847600  
www.gvs.com

## **E C Declaration of Conformity**

We declare that the undernoted Class I Medical Devices are in conformity with requirements and provisions of Medical Device Regulation (EU) 2017/745.

### **Device Description**

Products as per attached product schedule.

### **Directives:**

Medical Device Regulation (EU) 2017/745 via the route of Chapter III, Rule 1, products are Class I, and other applicable standards and regulatory requirements listed within the appropriate technical documentation.

EU Authorised Representative: GVS S.p.A, Via Roma 50, 40069 Zola Predosa, Bologna, Italy.

This Declaration of conformity is issued under the sole responsibility of the legal manufacturer.



Signed by.....  
Andrew Pearce  
GVS UK Quality and Regulatory Manager  
Morecambe, Lancashire, United Kingdom

Date: 29<sup>th</sup> September 2021

## **Product Schedule**

### **CPAP/BIPAP Replacement filters:**

7270 Series	Die-Cut Pads	506012095CPAP/BIPAP6A
7271 Series	Die-Cut High Speed Pads	506012095CPAP/BIPAP6A
7272 Series	Cut and Weld Pads	506012095CPAP/BIPAP6A

### **Basic UDI-DI:**

### **Pleated Mechanical Filters:**

1500/01	HEPA Filter	506012095PleatedMechNH
3200/03	Platinum Invacare	506012095PleatedMechNH
3200/08	Refill for EverFlo	506012095PleatedMechNH
3500/01	Ventilator Machine Pre-Filter	506012095PleatedMechNH
3700/02	Inogen Air Intake Filter	506012095PleatedMechNH
4100/20	Main Air Intake Filter	506012095PleatedMechNH
4100/25	Oxygen Concentrator Filter	506012095PleatedMechNH
4100/30	Oxygen Concentrator Filter	506012095PleatedMechNH
4100/92	Oxygen Concentrator Filter	506012095PleatedMechNH
4100/725	Oxygen Concentrator Filter	506012095PleatedMechNH
4100/735	Oxygen Concentrator Filter	506012095PleatedMechNH

### **Basic UDI-DI:**

### **Activated carbon filters:**

1898/01	Scavenger Filter	506012095ActivatedCarb9U
1898/03	Scavenger Filter	506012095ActivatedCarb9U
1898/09	Goebertus Scavenger Filter	506012095ActivatedCarb9U

### **Basic UDI-DI:**

### **Accessory:**

A508	Nose Clip	506012095AccessoriesJ10
------	-----------	-------------------------

### **Basic UDI-DI:**

### **Medical Facemask:**

SEGRE F31000	FFP3 Type IIR (EN 14683)	506012095F31000BC
--------------	--------------------------	-------------------

### **Basic UDI-DI:**