

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

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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 & Regulatory Manager Morecambe, Lancashire, United Kingdom Date: 12th May 2021

Product Schedule

CPAP/BIPAP Replacement filters:

7270 SeriesDie-Cut Pads7271 SeriesDie-Cut High Speed Pads7272 SeriesCut and Weld Pads

Pleated Mechanical Filters:

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

Activated carbon filters:

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

Accessory:

A508

Nose Clip