

| Product P/N | See page 1 | |
|-------------|--------------------------------------|----------|
| Description | Elipse EN Carbon Range (REV1 & REV2) | Mod. 984 |
| | | Rev. 06 |

Elipse EN Carbon Range (REV1 & REV2)

Certified to EN 140 & EN 14387



PRODUCT DESCRIPTION

Elipse Carbon Cartridge respirator range, consisting of:

- Combined particulate and activated carbon cartridge respirators giving protection against dust, mist and fume of all types, and micro-organism eg. Bacteria & Viruses and specific gasses & vapours.
- Activated carbon cartridge respirators giving protection against specific gasses & vapours.

REV1 Facemask Range (GVS Elipse Low Profile Combined Gas & Particulate Range):

- SPR338IFUE A1P3 S/M
- SPR503IFUC A1P3 M/L
- SPR425IFUD B1P3 S/M
- SPR505IFUC B1P3 M/L
- SPR580IFUA ABE1P3 S/M
- SPR581IFUA ABE1P3 M/L
- SPR673IFUA A2P3 S/M
- SPR674IFUA A2P3 M/L

REV1 Replacement Kit Range (GVS Elipse Low Profile Combined Gas & Particulate Range):

- SPR341IDUC A1P3 R D
- SPR426IDUC B1P3 R D
- SPR582IDUA ABE1P3 R D
- SPR675IDUA A2P3 R D

REV2 Facemask Range (GVS Elipse High Performance Gas / Combined Gas & Particulate Range):

- SPR487IFUA ABEK1 S/M
- SPR488IFUA ABEK1 M/L
- SPR490IFUA ABEK1P3 S/M
- SPR491IFUA ABEK1P3 M/L
- SPR495IFUA A2P3 S/M
- SPR496IFUA A2P3 M/L
- SPR511IFUA A1 S/M
- SPR512IFUA A1 M/L



| Product P/N | See page 1 | | |
|----------------------------|---|--|---|
| Description | Elipse EN Carbon Rang | e (REV1 & REV2) | Mod. 984 Rev. 06 |
| | SPR514IFUA – E SPR515IFUA – E SPR517IFUA – A SPR518IFUA – A | 1 M/L E1 S/M | |
| | REV2 Replacement Kit Re Range): SPR489IDUA – A SPR492IDUA – A SPR497IDUA – A SPR513IDUA – A SPR516IDUA – A | BEK1 BEK1P3 2P3 1 | nance Gas / Combined Gas & Particulate |
| | Similar existing product | t: □IN/A I□ISpecify: NIOSH RE I | /2 Range |
| MANUFACTURER NAME | GVS Filter Technology U | К | |
| INTENDED USE / APPLICATION | Standard EN 140 approved in acc (EU) 2016/425 a only when the a The Elipse half-n right hand filter dust, mist and fu | 0:1998, Regulation (EU) 2016/ ordance with European stand nd TP TC 019/2011. The device bove items are used together. nask is used together with a so s, to give protection against s | d half-mask in accordance with European 425 and TP TC 019/2011. The filters are ard EN 14387:2004+A1:2008, Regulation is approved for occupational applications of 2 non-handed filters / 1 left hand and 1 pecific gases, vapours, toxic dust particles, cteria and viruses where stated in the filter ayed on the filter label. |
| CLASS OF THE | - A combination of | of different gas filter types is p | ossible, information is available on request |
| PRODUCT | or via www.gvs. | | |
| | | | to be used for more than one shift. |
| | - Filters marked " | D" are resistant to dust cloggi | ng. 1 |
| | Type Colour | Application | |
| | P3 White | Hazardous and toxic dust particles. Dust, mist and fumes of all types, including bacteria and viruses. Also covers the protection provided by lower class P2 and P1 filters | |
| | A Brown | Organic gases and vapours, with boiling point ≥ 65°C | |
| | B Grey | Inorganic gases and vapours | |
| | E Yellow | Sulphur Dioxide and other acidic gases and vapours | |
| | K Green | derivatives | |
| | AX Brown | ≤ 65°C | |
| | NO-P3 Blue-Wh | | |
| | Hg-P3 Red-Wh | te Mercury | |



| Product P/N | See page 1 | |
|-----------------|--|-------------------------|
| Description | Elipse EN Carbon Range (REV1 & REV2) | Mod. 984 Rev. 06 |
| | | |
| | Protection provided by Class 2 and 3 filter includes that provided by the filter of lower class or classes. | e corresponding |
| | Gas Filter Maximum permissible detri- | |
| | Class Description mental gas concentration | |
| | Class 1 Low adsorption Capacity Max 0,1 % by volume | |
| | Class 2 Medium Max 0,5 % by volume | |
| | Class 3 High adsorption capacity Max 1,0 % by volume | |
| MATERIALS | Filter media: | |
| | □ N/A □ Specify: Activated Carbon Granules, PET/Glass Particulate m | edia. |
| | 10.020.0018: A - Activated Carbon Granules | |
| | 10.019.0072: AE - Activated Carbon Granules | |
| | 10.019.0075: ABEK - Activated Carbon Granules 10.020.0023: E - Activated Carbon Granules | |
| | 10.019.0058: B – Activated Carbon Granules | |
| | 10.020.0027: ABE – Activated Carbon Granules | |
| | 10.019.0079: A – High Performance Carbon Granules | |
| | 10.027.0012: PET/Glass Particulate media | |
| | Frame/Housing Polymer: | |
| | □ N/A □ Specify: Particulate Filter Overmould 10.054.0007– TPE, Care | tridge Case |
| | 10.053.0010 – ABS Colour: | |
| | □ N/A □ Specify: Facemask, Headband Pad, Head Cradle - Blue, Partie | culate Filters – White, |
| | Strap Support, Cartridge Case – Grey, Elastic Strap – Blue with logo | |
| | Other insert(s): | |
| | I N/A I Specify: Facemask, Headband Pad – TPE, Head Cradle – LDPI body – Polyamide, Valve Diaphragm – Silicone, Strap Support – Polypi | |
| | Strap, Cartridge Case – ABS | opylene, Liustic |
| | Regulatory Documentation Required: | |
| | □ Biocompatibility according ISO 10993-1 | |
| | I⊏I IMDS | |
| | I ROHS | |
| | I□ BSE/TSE | |
| | DEHP plasticizer Free and latex free | |
| | ☐ Aging | |
| | I REACH I Conflict minerals | |
| | Other: | |
| | □ N/A □ Specify: EN 140, EN 14387 | |
| PRODUCT | Appearance/Visual | |
| CHARACTERISTICS | Aesthetic part: | |
| | Yes; No | |
| | Finishing: | |
| | ☐ Trim finishing mirror polished surfaces ☐ Thin roughness surfaces | |
| | Gross roughness surface | |
| | ✓ As shown on drawing | |



| Product P/N | See page 1 | |
|-------------|--------------------------------------|----------|
| Description | Elipse EN Carbon Range (REV1 & REV2) | Mod. 984 |
| | | Rev. 06 |

Presence of graphics/Artwork: I No; I Specify: CE marking. Product Identification information on packaging including GVS business information, Notified Certification Body, Protection type, Lot expiry labels and information. Flash bears admitted: N/A Specify: **Refer to control the plan.** Injection gate vestige: □ N/A □ Specify: **Refer to control the plan.** Black spots admitted (size/area): N/A Specify: **Refer to control the plan.** Infiltration into insert admitted: □ N/A □ Specify: **Refer to control the plan.** Other: ■ N/A ■ Specify: Physical/Mechanical Dimensions: S/M Facemask (with Combined Filter) - D: 123mm x H: 126mm x W: 189mm M/L Facemask (with Combined Filter) - D: 123mm x H: 132mm x W: 189mm Filter Kit (Combined Filter) - D: 95mm x H: 62mm x W: 97mm Weight: S/M Facemask (with Combined Filter) – 394g M/L Facemask (with Combined Filter) - 399g Filter Kit (Combined Filter) – 246g Interfaces (ex: Input / Output connectors): N/A Specify: *Elipse cartridges designed to fit the Elipse facemask* Operating temperature Range: -10°C to 40°C Storage temperature Range: -10°C to 40°C Other: N/A Specify: **Humidity** <**95**% Chemical Compatibility to solvents: □ N/A □ Specify: *Mild soapy water, disinfectant*. Resistance to weathering: I N/A □ Specify: Other: ■ N/A ■ Specify: **Biological** Sterility: **I** N/A **I** Specify: Pyrogenicity: **I**N/A □ Specify: Haemolysis: ■ N/A ■ Specify: Toxicity: **I**N/A **I**Specify:



| Product P/N | See page 1 | |
|-------------|--------------------------------------|----------|
| Description | Elipse EN Carbon Range (REV1 & REV2) | Mod. 984 |
| | | Rev. 06 |

| - | |
|----------------|--|
| | |
| | Functional |
| | Air Flow Rate: |
| | □ N/A □ Specify: Tested to 95 I/min as per EN 140 and EN 14387 |
| | Water Break Through Pressure: |
| | IIIN/A □ Specify: |
| | |
| | Liquid Flow Rate: |
| | IPIN/A IPISpecify: |
| | Bubble Point Pressure: |
| | I N/A I Specify: |
| | Filtration Efficiency: |
| | N/A Fi Specify: Filter Efficiency @ 47.5 I/min, min. 99.95% (EN 14387) |
| | Pressure Drop: |
| | · · |
| | N/A Specify: Breathing Resistance @ 95 I/min (2 filters), max. 8.2 mbar |
| | Internal Volume: |
| | I N/A I Specify: |
| | Operating Lifetime: |
| | □N/A □Specify: |
| | Filters should be changed once a month or more frequently if you find an increased |
| | resistance to breathing as the filters become clogged; when you start to smell gas / vapour |
| | indicating that the filters are exhausted; or if they reach the end of their 3 year expiry date, |
| | |
| | which is marked on each individual filter and product packaging. |
| | Shelf Lifetime: |
| | □ N/A I Specify: 3 years from the date of manufacture. |
| | Other: |
| | ■N/A □Specify: |
| | |
| | |
| | Cleanliness |
| | Part cleanliness: |
| | N/A ISpecify: Refer to control the plan. |
| | Clean-room Production required: |
| | ✓ N/A □ Specify: |
| | FEITIVA FEISPECHY. |
| | |
| | Testing |
| | Insert embedding Test: |
| | I N/A I Specify: |
| | Burst test: |
| | IFIN/A IFI Specify: |
| | Leakage: |
| | |
| | IFIN/A IFISpecify: |
| | Other: |
| | N/A Specify: Refer to control the plan and test plan QAF 7/96 |
| | |
| INSTRUCTIONS / | IFU |
| WARNINGS | □N/A □Required: Specify Languages: |
| | ☐ English ☐ French ☐ Italian ☐ Spanish ☐ Portuguese ☐ German ☐ Chinese ☐ |
| | , |
| | Japanese Korean Russian Other (Specify): Polish, Dutch, Swedish, Finnish, |
| | Norwegian, Danish, Turkish, Czech, Slovak, Hungarian, Bosnian, Romanian, |
| | Lithuanian, Latvian, Estonian, Greek, Bulgarian, Serbian, Croatian, Icelandic, |
| | Albanian, Arabic, Hebrew. |
| | |
| | |

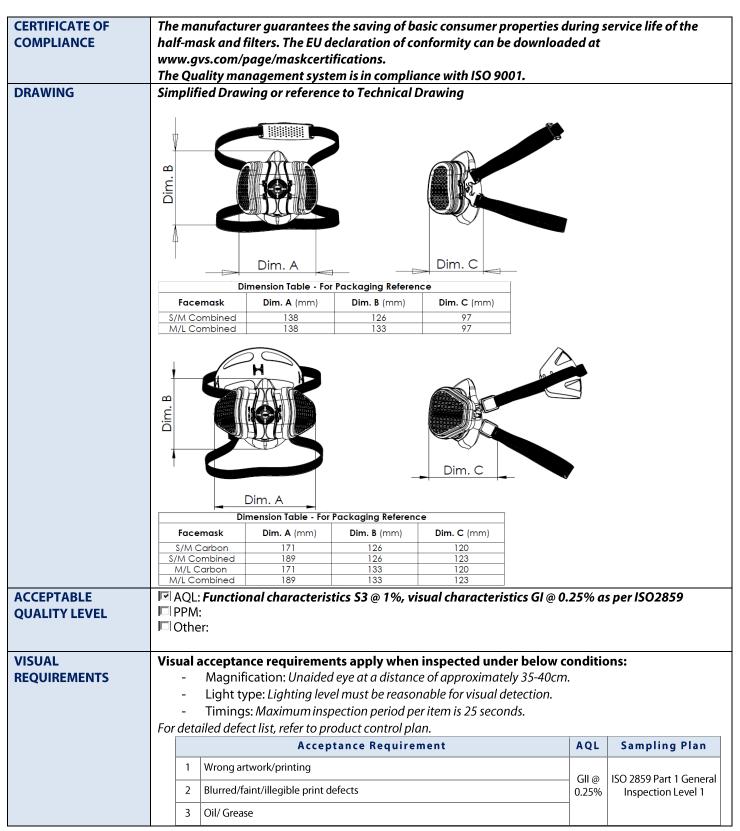


| Product P/N | See page 1 | |
|-------------|--------------------------------------|----------|
| Description | Elipse EN Carbon Range (REV1 & REV2) | Mod. 984 |
| | | Rev. 06 |

| DDODUCT CHELE LIFE | 2 and also data also annotations |
|-----------------------------|---|
| PRODUCT SHELF LIFE | 3 years of the date of manufacture. Expiration date and date of manufacture are detailed on the product labelling. |
| STERILIZATION | Expiration date and date of manufacture are detailed on the product iddenning. |
| JIEMELE/KITOK | IF Not required; IF EtO; IF Gamma; IF Beta; IF Steam; IF e-beam |
| APPLICABLE | Product Certification required: |
| STANDARDS AND | I CE mark |
| REGULATIONS | I□ FDA |
| | □ Canadian Health |
| | I□ Brazil ANVISA |
| | I□ Argentina ANMAT |
| | I□NIOSH |
| | I□ Japan |
| | I□ Korea |
| | I□ China |
| | I Russia |
| | □ Other (Specify): |
| | Applicable Standards and Technical Regulations: |
| | Regulation (EU) 2016/425 on personal protective equipment |
| | EN 140:1998 Respiratory protective devices – Half masks and quarter masks – |
| | Requirements, testing, marking |
| | • EN 14387:2004+A1:2008 Respiratory protective devices – Gas filters and combined filters – |
| | Requirements, testing, marking |
| | • TP TC 019/2011 |
| | Customer Specific Requirements: See Opsial Facemask and Replacement Kits Range |
| | Is the Product a safety product? |
| | ✓ Yes ☐ No |
| | Environment Impact: Have atmosphere emissions, liquid effluents, underground leachables been considered? |
| | Energy released (heat, vibration): |
| | □ Yes □ No |
| INTELECTUAL PROPERTY AND | Intellectual Property: Patents that have been granted or applied for that must be considered. |
| FUNDING | Grants: Is the project (partially) funded by public institutions? |
| TONDING | ■ N/A ■ Specify: |
| PACKAGING AND | Packaging |
| LABELING | □ Primary: Individual box (1 mask) / Replacement kit bag (2 filters) |
| | Secondary: Bulk box (10 masks / 10 replacement kits) |
| | Labelling: |
| | Standard; □ Customer specific: |
| | UDI: |
| | □ N/A; □ No; □ Yes (Specify): Standard SAP label |



| Product P/N | See page 1 | |
|-------------|--------------------------------------|----------|
| Description | Elipse EN Carbon Range (REV1 & REV2) | Mod. 984 |
| | | Rev. 06 |





| Product P/N | See pa | | |
|-----------------|------------------|---|--|
| Description | Elipse I | EN Carbon Range (REV1 & REV2) | Mod. 984 |
| | | | Rev. 06 |
| | 4 | Incorrect colour | |
| | 5 | Discolouration | - |
| | 6 | Surface damage | - |
| | 7 | Packaging damage | - |
| | 8 | Flow marks/ Marbling | - |
| | 9 | Deformation / distortion | - |
| | 10 | Dirt | - |
| | 11 | Insert missing | - |
| | 12 | Damaged/broken item | - |
| | 13 | Incorrect assembly sequence | - |
| GENERAL SAFETY | | I characteristic: Product characteristic which can affect safety or com | nliance with regulations fit |
| AND PERFORMANCE | - | n, performance or subsequent processing of product. | phanee with regulations, m, |
| REQUIREMENTS | | l Characteristic # 01: Filter efficiency (combined cartridges only) | |
| | Specia Specia | P3 Filter Efficiency @ 95 I/min (Sodium Chloride) = 99.95% as per EN 1 average = 99.995%) P3 Filter Efficiency @ 95 I/min (Paraffin Oil) = 99.95% as per EN 143 (G 99.995%) I Characteristic # 02: Gas performance A1 Gas Performance, C ₆ H ₁₂ – minimum breakthrough time 70 minute A2 Gas Performance, Cl ₂ – minimum breakthrough time 35 minute B1 Gas Performance, Cl ₂ – minimum breakthrough time 20 minutes, breakthrough time 40 minutes, HCN – minimum breakthrough time 20 minutes E1 Gas Performance, SO ₂ – minimum breakthrough time 20 minutes K1 Gas Performance, NH ₃ – minimum breakthrough time 50 minutes I Characteristic # 03: Breathing resistance Breathing Resistance @ 30 I/min (2 filters) = max. 2.2 mbar as per EN Breathing Resistance after Clogging @ 95 I/min (2 filters) = max. 9.0 m I Characteristic # 04: Mass of filters Mass of the Filters to be used with a half mask = max. 300 g as per EN I Characteristic # 05: TIL Total Inwards Leakage = max. 5% inwards leakage as per EN 140 I Characteristic # 06: Other EN 140 requirements Temperature Conditioning as per EN 140 (QAF 7/66) | EVS performance average = es as per EN 14387 es as per EN 14387 H₂S − minimum 25 minutes as per EN 14387 as per EN 14387 as per EN 14387 143 143 143 nbar as per EN 143 |
| | - | Head Harness as per EN 140 (QAF 7/68) | |
| | - | Facemask Integrity (combined filters only) – additional batch test as Mechanical Strength as per EN 140 (QAF 7/105) | per QAF 7/70 |
| | - | Inhalation/ Exhalation Valve (Flow) as per EN 140 (QAF 7/86, QAF 7/1 | 106) |



| Product P/N | See page 1 | |
|-------------|--------------------------------------|----------|
| Description | Elipse EN Carbon Range (REV1 & REV2) | Mod. 984 |
| | | Rev. 06 |

| - Exhalation Valve (Strength) as per EN 140 (QAF 7/107) |
|--|
| - Flammability as per EN 140 |
| - Carbon Dioxide Content of Inhalation Air as per EN 140 |
| |

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

REVISIONS AND APPROVALS:

| DATE | REV. | REASON FOR CHANGE | ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE) | APPROVED BY: (NAME/FUNCTION/SIGNATURE) |
|------------|------|---|---|--|
| 02/11/2016 | 1 | First issue at high industrial stage | Andrew Calland / Leade Engineer | Rebecca Law / QA Manager |
| 08/06/2020 | 2 | General update with 30 language IFU and new cradle. Addition of REV1 range and removal of EN 405 products (see separate specifications) | Ondrej Kalensky / Project Engineer | Andrew Pearce / QA Manager |
| 17/09/2021 | 3 | Addition of REV1 A2P3 cartridge range. | Ondrej Kalensky / Project Engineer | Andrew Pearce / QA Manager |