PRODUCT SPECIFICATION

Product P/N	**See page 1**	**Mod. 984 Rev. 06**
Description	**Elipse EN Integra Range (Particulate, REV1 & REV2)**	

Elipse EN Integra Range (REV1 & REV2)

Certified to EN 140, EN 166, EN 143 & EN 14387



PRODUCT DESCRIPTION	***Elipse Integra is a half mask combined with eye protection complying to European Standards EN 140 and EN 166. This mask in used only with Elipse filters / cartridges in place.*** **Integra P3 Facemask Range (Optical Class 2, Impact F):** • **SPR404IFUC – P3 Nuisance Odour S/M** • **SPR405IFUC – P3 Nuisance Odour M/L** • **SPR406IFUC – P3 M/L** • **SPR407IFUC – P3 S/M** **Integra REV1 Facemask Range (Optical Class 2, Impact F):** • **SPR444IFUC – A1P3 S/M** • **SPR401IFUC – A1P3 M/L** **Integra REV2 Facemask Range (Optical Class 2, Impact F):** • **SPR534IFUA – ABEK1P3 S/M** • **SPR535IFUA – ABEK1P3 M/L** • **SPR536IFUA – A2P3 S/M** • **SPR537IFUA – A2P3 M/L** • **SPR538IFUA – ABEK1 S/M** • **SPR539IFUA – ABEK1 M/L** **Integra P3 Facemask Range (Optical Class 1, Impact B):** • **SPR404IFUD – P3 Nuisance Odour S/M** • **SPR405IFUD – P3 Nuisance Odour M/L** • **SPR406IFUD – P3 M/L** • **SPR407IFUD – P3 S/M** **Integra REV1 Facemask Range (Optical Class 1, Impact B):** • **SPR444IFUD – A1P3 S/M** • **SPR401IFUD – A1P3 M/L**

	• **SPR583IFUA – ABE1P3 S/M** • **SPR584IFUA – ABE1P3 M/L** **Integra REV2 Facemask Range (Optical Class 1, Impact B):** • **SPR534IFUB – ABEK1P3 S/M** • **SPR535IFUB – ABEK1P3 M/L** • **SPR536IFUB – A2P3 S/M** • **SPR537IFUB – A2P3 M/L** • **SPR538IFUB – ABEK1 S/M** • **SPR539IFUB – ABEK1 M/L** **Similar existing product:** ☐ N/A ☑ Specify: ***Integra NIOSH / ANSI Range***
MANUFACTURER NAME	***GVS Filter Technology UK Ltd.***
INTENDED USE / APPLICATION	***Integra P3 Facemask Range*** - ***The GVS Elipse Integra particulate safety respirator is approved as a half-mask with eye protector, in accordance with European Standards EN 140:1998, EN 166:2001, Regulation (EU) 2016/425 and TP TC 019/2011. The GVS Elipse HESPA air filter is approved as a particle filter in accordance with European Standard EN 143:2000+A1:2006, Regulation (EU) 2016/425 and TP TC 019/2011. The device is approved for occupational applications only when the above items are used together.*** - ***The GVS Elipse Integra half-mask together with HESPA particulate air filters give protection against both solid and liquid hazardous and toxic dust particles, metal fumes, mist and micro-organisms (e.g. bacteria and viruses).*** ***Integra REV1/REV2 Facemask Range*** - ***The GVS Elipse Integra particulate safety respirator is approved as a half-mask with eye protector, in accordance with European Standards EN 140:1998, EN 166:2001, Regulation (EU) 2016/425 and TP TC 019/2011. The filters are approved in accordance with European standard EN 14387:2004+A1:2008, Regulation (EU) 2016/425 and TP TC 019/2011. The device is approved for occupational applications only when the above items are used together.*** - ***The GVS Elipse Integra half-mask is used together with a set of 2 non-handed filters, to give protection against specific gases, vapours, toxic dust particles, dust, mist and fumes of all types, including bacteria and viruses where stated in the filter description and indicated by the colours displayed on the filter label.***
CLASS OF THE PRODUCT	***Integra P3 Facemask Range*** - ***The P3 classification provides minimum efficiency of 99.95% and is symbolised by white colour code. The protection provided by classification P3 also covers the protection provided by lower class P2 and P1 filters.*** - ***Filters marked "R" are re-usable and intended to be used for more than one shift.*** - ***Filters marked "D" are resistant to dust clogging.*** - ***The eye protector is suited for use as listed in the frame marking.***

Mark	Meaning
GVS	Manufacturer's ID
1, 2, 3	Optical Class (1 = high, 2 = medium, 3 = low)
3	Protection against droplets and splashes of liquids
4	Protection against large dust particles
5	Protection against gas and fine dust particles
8	Protection against short circuit electric arc
9	Protection against molten metals and hot solids
b	Protection against optical radiation
S	Increased robustness
F	Low energy impact
B	Medium energy impact
A	High energy impact
T	Protection against high speed particles at extremes of temperature
K	Resistance to surface damage by fine particles
N	Resistance to fogging

Integra REV1/REV2 Facemask Range

- ***A combination of different gas filter types is possible, information is available on request or via www.gvs.com.***
- ***Filters marked "R" are re-usable and intended to be used for more than one shift.***
- ***Filters marked "D" are resistant to dust clogging.***

Filter 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	Ammonia and organic ammonia derivatives
AX	Brown	Gases and vapours from organic compounds, with low boiling point ≤ 65°C
NO-P3	Blue-White	Nitrogen oxides, e.g. NO, NO2, NOx
Hg-P3	Red-White	Mercury

- ***Protection provided by Class 2 and 3 filter includes that provided by the corresponding filter of lower class or classes.***

Gas Filter Class	Description	Maximum permissible detri-mental gas concentration
Class 1	Low adsorption capacity	Max 0,1 % by volume
Class 2	Medium adsorption capacity	Max 0,5 % by volume
Class 3	High adsorption capacity	Max 1,0 % by volume

- ***The eye protector is suited for use as listed in the frame marking (refer to specification table for goggle above)***

MATERIALS

Filter media:

☐ N/A ☑ Specify: ***Activated Carbon Granules, PET/Glass Particulate media.***
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 ***10.027.0012: PET/Glass Particulate media*** ***Polycarbonate with coating: lens*** **Frame/Housing Polymer**: ☐ N/A ☑ Specify: ***Particulate Filter Overmould 10.054.0007– TPE, Cartridge Case 10.053.0010 – ABS, Goggle frame - TPU*** **Colour:** ☐ N/A ☑ Specify: ***Facemask, Goggle Frame, Headband Pad, Head Cradle - Blue, Particulate Filters – White, Strap Support, Cartridge Case – Grey, Elastic Strap – Blue with logo*** **Other insert(s):** ☐ N/A ☐ Specify: ***Facemask, Headband Pad – TPE, Head Cradle – LDPE, Turnbuckle, Valve body – Polyamide, Valve Diaphragm – Silicone, Strap Support – Polypropylene, Elastic Strap, Cartridge Case – ABS*** **Regulatory Documentation Required:** ☐ Biocompatibility according ISO 10993-1 ☐ IMDS ☑ ROHS ☐ BSE/TSE ☑ DEHP plasticizer Free and latex free ☐ Aging ☑ REACH ☑ Conflict minerals **Other:** ☐ N/A ☑ Specify: ***EN 140, EN 166, EN 143, EN 14387***
PRODUCT CHARACTERISTICS	**Appearance/Visual** Aesthetic part: ☑ Yes; ☐ No Finishing: ☐ Trim finishing mirror polished surfaces ☐ Thin roughness surfaces ☐ Gross roughness surface ☑ As shown on drawing Presence of graphics/Artwork: ☐ No; ☑ 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** ***S/M Particulate variants*** ***Weight: <208g***

M/L Particulate variants
Weight: <210g

S/M REV1/REV2 variants
Weight: <461g

M/L REV1/REV2 variants
Weight: <469 g
See simplified drawing for product dimensions.

Interfaces (ex: Input / Output connectors):
☐ N/A ☑ Specify: ***Elipse filters and 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:
☑ N/A ☐ Specify:
Other:
☑ N/A ☐ Specify:

Biological

Sterility:
☑ N/A ☐ Specify:
Pyrogenicity:
☑ N/A ☐ Specify:
Haemolysis:
☑ N/A ☐ Specify:
Toxicity:
☑ N/A ☐ Specify:

Functional

Air Flow Rate:
☐ N/A ☑ Specify: ***Tested to 95 l/min as per EN 140, EN 143 and EN 14387***
Water Break Through Pressure:
☑ N/A ☐ Specify:
Liquid Flow Rate:
☑ N/A ☐ Specify:
Bubble Point Pressure:
☑ N/A ☐ Specify:
Filtration Efficiency:
☐ N/A ☑ Specify: ***Filter Efficiency @ 47.5 l/min, min. 99.95% (EN 14387)***
Pressure Drop:
☐ N/A ☑ Specify: ***Breathing Resistance @ 95 l/min (2 filters), max. 4.2 mbar as per EN 143, Breathing Resistance @ 95 l/min (2 filters), max. 8.2 mbar as per EN 14387.***

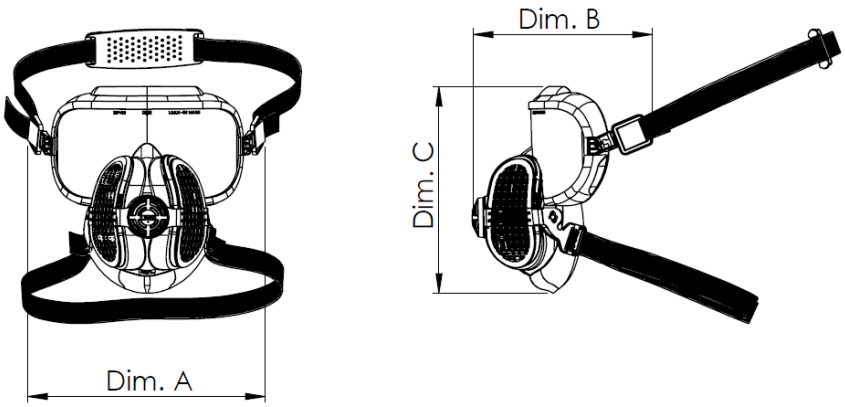
	Internal Volume: ☑ N/A ☐ Specify: Operating Lifetime: ☐ N/A ☑ Specify: ***REV1/REV2 Facemask Range*** - ***Filters should be changed once a month or more frequently if you find an increased resistance to breathing as the filters become clogged; when you start to smell gas / vapour indicating that the 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.*** ***Particulate Facemask Range*** - ***Filters must be changed once a month or more frequently if you find a resistance to breathing as the filter becomes clogged or if they reach the end of their expiry date.*** Shelf Lifetime: ☐ N/A ☐ Specify: ***REV1/REV2 Facemask Range*** - ***3* years from the date of manufacture.** ***Particulate Facemask Range*** - ***5* years from the date of manufacture.** Other: ☑ N/A ☐ Specify: **Cleanliness** Part cleanliness: ☐ N/A ☑ Specify: ***Refer to control the plan.*** Clean-room Production required: ☑ N/A ☐ Specify: **Testing** Insert embedding Test: ☑ N/A ☐ Specify: Burst test: ☑ N/A ☐ Specify: Leakage: ☑ N/A ☐ Specify: Other: ☐ N/A ☑ Specify: ***Refer to control the plan and test plan QAF 7/96 and QAF 7/113***
INSTRUCTIONS / WARNINGS	**IFU** ☐ 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 SHELF LIFE	***REV1/REV2 Facemask Range*** - ***3* years from the date of manufacture.** ***Particulate Facemask Range*** - ***5* years from the date of manufacture.**

	Expiration date and date of manufacture are detailed on the product labelling.
STERILIZATION	☑ Not required; ☐ EtO; ☐ Gamma; ☐ Beta; ☐ Steam; ☐ e-beam
APPLICABLE STANDARDS AND REGULATIONS	**Product Certification required:** ☑ CE mark ☐ FDA ☐ Canadian Health ☐ Brazil ANVISA ☐ Argentina ANMAT ☐ NIOSH ☐ Japan ☐ Korea ☐ China ☑ 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 166:2001 Personal eye-protection - Specifications*** • ***EN 143:2000 Respiratory protective devices – Particle filters – 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 Integra Facemask Range*** **Is the Product a safety product?** ☑ Yes ☐ No **Environment Impact:** Have atmosphere emissions, liquid effluents, underground leachables been considered? ☑ Yes ☐ No **Energy released (heat, vibration):** ☐ Yes ☑ No
INTELECTUAL PROPERTY AND FUNDING	**Intellectual Property:** Patents that have been granted or applied for that must be considered. ☑ N/A ☐ Specify: **Grants:** Is the project (partially) funded by public institutions? ☑ N/A ☐ Specify:
PACKAGING AND LABELING	**Packaging** ☑ Primary: ***Individual box (1 mask)*** ☑ Secondary: ***Bulk box (5 Particulate / REV1 masks, 4 REV2 masks)*** **Labelling**: ☑ Standard; ☐ Customer specific:

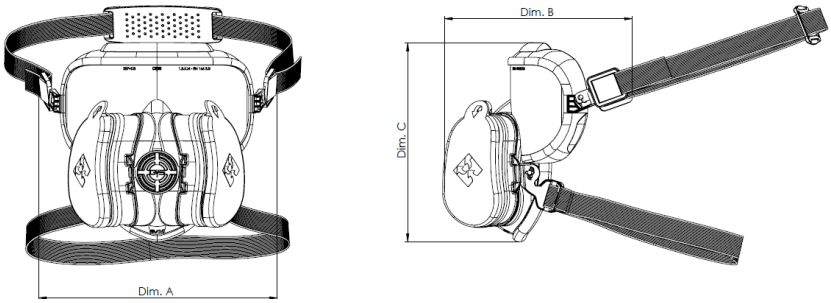
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	UDI: ☐ N/A; ☐ No; ☑ Yes (Specify): ***Standard SAP label***
CERTIFICATE OF COMPLIANCE	***The manufacturer guarantees the saving of basic consumer properties during service life of the half-mask and filters. The EU declaration of conformity can be downloaded at www.gvs.com/page/maskcertifications.*** ***The Quality management system is in compliance with ISO 9001, ISO 13485.***
DRAWING	***Simplified Drawing or reference to Technical Drawing***



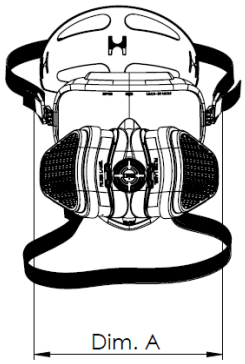
Dimension Table - For Packaging Reference			
Facemask	**Dim. A** (mm)	**Dim. B** (mm)	**Dim. C** (mm)
Integra S/M Particulate	200	152	168
Integra M/L Particulate	200	152	174

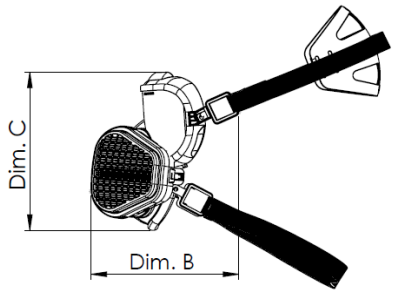


Dimensions Table - For Packaging Reference			
Description	**Dimensions**		
	Dim. A (mm)	**Dim. B (mm)**	**Dim. C (mm)**
Integra S/M Mask with REV1 Cartridges	200	147	168
Integra M/L Mask with REV1 Cartridges	200	149	174

PRODUCT SPECIFICATION

Product P/N	**See page 1**	**Mod. 984 Rev. 06**
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Dimension Table - For Packaging Reference			
Description	Dim. A (mm)	Dim. B (mm)	Dim. C (mm)
Integra S/M Mask with Combined Cartridges	200	153	168
Integra M/L Mask with Combined Cartridges	200	157	174
Integra S/M Mask with Carbon Cartridges	200	151	168
Integra M/L Mask with Carbon Cartridges	200	155	174

ACCEPTABLE QUALITY LEVEL

☑ AQL: ***Functional characteristics S3 @ 1%, visual characteristics GI @ 0.25% as per ISO2859***
☐ PPM:
☐ Other:

VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

- Magnification: *Unaided eye at a distance of approximately 35-40cm.*
- Light type: *Lighting level must be reasonable for visual detection.*
- Timings: *Maximum inspection period per item is 25 seconds.*

For detailed defect list, refer to product control plan.

	Acceptance Requirement	AQL	Sampling Plan
1	Wrong artwork/printing	GII @ 0.25%	ISO 2859 Part 1 General Inspection Level 1
2	Visual Inspection & Construction, Lens Surface quality, Information, Packaging & Marking		
3	Blurred/faint/illegible print defects		
4	Oil/ Grease		
5	Incorrect colour		
6	Discolouration		
7	Surface damage		
8	Packaging damage		
9	Flow marks/ Marbling		
10	Deformation / distortion		
11	Dirt		

12	Insert missing			
13	Damaged/broken item			
14	Incorrect assembly sequence			

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

Special characteristic: *Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.*

Special Characteristic # 01: *Filter efficiency (particulate filters and combined cartridges only)*

- *P3 Filter Efficiency @ 95 l/min (Sodium Chloride) = 99.95% as per EN 143 (GVS performance average = 99.995%)*
- *P3 Filter Efficiency @ 95 l/min (Paraffin Oil) = 99.95% as per EN 143 (GVS performance average = 99.995%)*

Special Characteristic # 02: *Gas performance*

- *A1 Gas Performance, C_6H_{12} – minimum breakthrough time 70 minutes as per EN 14387*
- *A2 Gas Performance, C_6H_{12} – minimum breakthrough time 35 minutes as per EN 14387*
- *B1 Gas Performance, Cl_2 – minimum breakthrough time 20 minutes, H_2S – minimum breakthrough time 40 minutes, HCN – minimum breakthrough time 25 minutes as per EN 14387*
- *E1 Gas Performance, SO_2 – minimum breakthrough time 20 minutes as per EN 14387*
- *K1 Gas Performance, NH_3 – minimum breakthrough time 50 minutes as per EN 14387*

Special Characteristic # 03: *Breathing resistance*

- *Breathing Resistance @ 30 l/min (2 filters) = max. 2.2 mbar as per EN 143*
- *Breathing Resistance @ 95 l/min (2 filters) = max. 8.2 mbar as per EN 143*
- *Breathing Resistance after Clogging @ 95 l/min (2 filters) = max. 9.0 mbar as per EN 143*

Special Characteristic # 04: *Mass of filters*

- *Mass of the Filters to be used with a half mask = max. 300 g as per EN 143*

Special Characteristic # 05: *TIL*

- *Total Inwards Leakage = max. 5% inwards leakage as per EN 140*

Special Characteristic # 06: *Other EN 140 requirements*

- *Temperature Conditioning as per EN 140 (QAF 7/66)*
- *Head Harness as per EN 140 (QAF 7/68)*
- *Facemask Integrity (combined filters only) – additional batch test as per QAF 7/70*
- *Mechanical Strength as per EN 140 (QAF 7/105)*
- *Inhalation/ Exhalation Valve (Flow) as per EN 140 (QAF 7/86, QAF 7/106)*
- *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*

Special Characteristic # 07: *EN 166 requirements*

- *Spherical, astigmatic & prismatic refractive powers (optical class 1 & 2 as applicable) as per EN 166*

Product P/N	**See page 1**	**Mod. 984 Rev. 06**
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	- *Protection against high-speed particles (grade B & F as applicable) as per EN 166* - *Stability at elevated temperature as per EN 166* - *Resistance to surface damage by fine particles as per EN 166* - *Transmittance as per EN 166* - *Diffusion of light as per EN 166* - *Quality of material and surface as per EN 166* - *Resistance to ultraviolet radiation (U-V conditioning) as per EN 166* - *Resistance to ignition as per EN 166* - *Protection against droplets and splashes of liquids as per EN 166* - *Protection against gases and fine dust particles as per EN 166* - *Resistance to fogging of oculars as per EN 166*
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)
31/01/2019	0	First Issue for quotation	Ondrej Kalensky, Project Engineer	Andrew Calland, Lead Engineer
14/01/2019	1	Updated to new Mod. 984 revision. Document reviewed for industrialization.	Ondrej Kalensky, Project Engineer	Andrew Pearce, QA Manager
08/06/2020	2	Specification updated with all Integra variants (class 1 impact B and class 2 impact F). IFU updated with 30 languages. Head cradle added.	Ondrej Kalensky / Project Engineer 	Andrew Pearce / QA Manager 