

EU DECLARATION OF CONFORMITY

According to EU Regulation 2016/425 on PPE & Regulation (EU) 2017/745 of 5th April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC



ALPHA HX-2 & HX-3 Series
Disposable Fold-Flat Respirator
Type IIR

Note:

x-2 = FFP2

x-3 = FFP3

Basic UDI-DI (HX-2)
506041498HX2EB
UDI-DI
05060414987217 [GS1]

Basic UDI-DI (HXL-2)
50567394HXL2RJ
UDI-DI
05056739445679 [GS1]

Basic UDI-DI (HX-3)
506041498HX3ED
UDI-DI
05060414987231 [GS1]

Basic UDI-DI (HXL-3)
506041498HXL396
UDI-DI
05060414988504 [GS1]

The legal manufacturer

AlphaSolway Ltd
Factory 1,
Queensberry Street, Annan,
DG12 5BL,
UK
SRN GB-MF-000019916

Authorised (EU) Representative

Globus EMEA Ltd
51 Dawson St Dublin
D02 AN25
Ireland
SRN IE-AR-000002785

confirms that the listed product(s)

Conform(s) to

PPE (EU) Regulation 2016/425

And standard(s)

EN 149:2001+A1:2009

The Notified Body

CCQS Certification Services Limited [2834]

performed the EU type-examination, (Module B), and issued the EU type- examination certificate:

CE-PI-20200723-01-01-9I

The PPE is subject to the conformity assessment procedure, conformity to type based on quality assurance of the production process, (Module D), under the surveillance of the notified body

SGS Fimko Oy Finland [0598]

and

Conform(s) to

Medical Devices Regulation (EU) 2017/745
as amended (effective from 26/05/2021)

And harmonised standard(s)

EN 14683:2019+AC:2019

Intended Purpose

Non-Sterile Disposable Respirator intended to reduce the transmission of airborne particles and droplets in healthcare or clinical environments. The product is designed for both medical and personal protective applications.

Risk Class

Class I

Classification Rule

Rule 1

Sterile

No

Measuring Function

No

Reusable

No

Conformity Assessment Route

This EU Declaration of Conformity (MDR) is

This declaration of conformity is issued under the sole responsibility of the manufacturer.

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issued in accordance with Regulation (EU) 2017/745 (MDR). The conformity assessment to MDR has been performed as a self-certification in accordance with Annex II and Annex III (Technical Documentation).

Signed on behalf of the manufacturer

J.Magniez

Head of Regulatory & Quality

29/06/2026



This declaration of conformity is issued under the sole responsibility of the manufacturer.

EN	EU DECLARATION OF CONFORMITY	LV	ES ATBILSTĪBAS DEKLARĀCIJA
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	LT	ES ATITIKTIES DEKLARACIJA NR.
ES	DECLARACIÓN UE DE CONFORMIDAD	HU	SZ. EU-MEGFELELŐSÉGI NYILATKOZAT
CS	EU PROHLÁŠENÍ O SHODĚ	MT	DIKJARAZZJONI TAL-KONFORMITÀ TAL-UE
DA	EU-OVERENSSTEMMELSESERKLÆRING	NL	EU-CONFORMITEITSVERKLARING
DE	EU-KONFORMITÄTSEERKLÄRUNG	PL	DEKLARACJA ZGODNOŚCI UE
ET	ELI VASTAVUSDEKLARATSIOON	PT	DECLARAÇÃO DE CONFORMIDADE UE
EL	ΣΥΜΒΟΥΛΙΟΥ ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	RO	DECLARAȚIA DE CONFORMITATE UE
FR	DÉCLARATION UE DE CONFORMITÉ	SK	EÚ VYHLÁSENIE O ZHODE
GA	DEARBHÚ COMHRÉIREACHTA Uimh.	SL	IZJAVA EU O SKLADNOSTI
HR	EU IZJAVA O SUKLADNOSTI	FI	EU-VAATIMUSTENMUKAISUUSVAKUUTUS
IT	DICHIARAZIONE DI CONFORMITÀ UE	SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

EN	PPE (product, type, batch or serial number):	HX-SERIES RANGE HX-2, HX-3, HXL-2, HXL-3, HX-3V, HXL-3V, HX-2V, HXL-2V
BG	ЛПС (продуктов, типов, партиден, или сериен номер):	
ES	EPI (número de producto, tipo, lote o serie):	
CS	OOP (výrobek, typ, šarže nebo sériové číslo):	
DA	PV (produkt-, type-, parti- eller serienummer):	
DE	PSA (Produkt-, Typen-, Chargen- oder Seriennummer):	
ET	Isikukaitsevahend (toote-, tüübi-, partii- või seerianumber):	
EL	ΜΑΠ (αριθμός προϊόντος, τύπου, παρτίδας ή σειράς):	
FR	EPI (numéro de produit, de type, de lot ou de série):	
GA	TCP (uimhir táirge, uimhir chineáil, baiscuimhir nó sraithuimhir):	
HR	OZO (proizvod, tip, serija ili serijski broj):	
IT	DPI (numero del prodotto, del tipo, del lotto o di serie):	
LV	IAL (ražojuma, tipa, partijas vai sērijas numurs):	
LT	AAP (gaminio, tipo, partijos, ar serijos numeris):	
HU	Egyéni védőeszköz (termék-, típus-, tétel- vagy sorozatszám):	
MT	PPE (numru tal-prodott, tip, lott jew serje):	
NL	PBM (product-, type-, partij- of serienummer):	
PL	ŚOI (numer produktu, typu, partii lub numer seryjny):	
PT	EPI (Número do produto, do tipo, do lote ou da série):	
RO	EIP (numărul produsului, tipului, lotului sau numărul de serie):	
SK	OOP (číslo výrobku, typu, šarže, alebo série):	
SL	Osebna varovalna oprema (proizvod, tip, serija ali serijska številka):	
FI	Henkilönsuojain (tuote-, tyyppi-, erä- tai sarjanumero):	
SV	Personlig skyddsutrustning (produkt-, typ-, parti- eller serienummer):	

EN	is in conformity with the relevant Union harmonization legislation: Personal Protective Equipment (PPE) - Regulation (EU) 2016/425
BG	е в съответствие със съответното законодателство на Съюза за хармонизация: Личните Предпазни Средства (ЛПС) - Регламент (ЕС) 2016/425
ES	es conforme con la legislación de armonización de la Unión aplicable: Equipos de Protección Individual (EPI) - Reglamento (UE) 2016/425
CS	je v souladu s příslušnými harmonizačními právními předpisy Unie: Osobních Ochranných Prostředcích (OOP) - Nařízení (EU) 2016/425
DA	er i overensstemmelse med den relevante EU-harmoniseringslovgivning: Personlige Værnemidler (PV) - Forordning (EU) 2016/425
DE	Gegenstand der Erklärung entspricht den einschlägigen Harmonisierungsrechtsvorschriften der Union: Persönliche Schutzausrüstungen (PSA) - Verordnung (EU) 2016/425
ET	on kooskõlas asjakohaste liidu ühtlustamisõigusaktidega: Isikukaitsevahendeid - Määrus (EL) 2016/425
EL	είναι σύμφωνο με τη σχετική ενωσιακή νομοθεσία εναρμόνισης: τα Μέσα Ατομικής Προστασίας (ΜΑΠ) - Κανονισμός (ΕΕ) 2016/425
FR	est conforme à la législation d'harmonisation de l'Union applicable: Équipements de Protection Individuelle (EPI) - Règlement (UE) 2016/425
GA	i gcomhréir le reachtaíocht ábhartha an Aontais um chomhchuibhiú: Trealamh Cosanta Pearsanta (TCP) - Rialachán (AE) 2016/425
HR	összhangban van a vonatkozó uniós harmonizációs jogszabályokkal: Osobnoj Zaštitnoj Opremi (OZO) - Uredba (EU) 2016/425

IT	è conforme alla pertinente normativa di armonizzazione dell'Unione: Dispositivi di Protezione Individuale (DPI) - Regolamento (UE) 2016/425
LV	atbilst attiecīgajiem Savienības saskaņošanas tiesību aktiem: Individuālajiem Aizsardzības Līdzekļiem (IAL) - Regula (ES) 2016/425
LT	atitinka atitinkamus derinamus Sąjungos teisės aktus: Asmeninių apsaugos priemonių (AAP) - Reglamentas (ES) 2016/425
HU	összhangban van a vonatkozó uniós harmonizációs jogszabályokkal: Egyéni védőeszköz - (EU) 2016/425 Rendelete
MT	hija konformi mal-leġiżlazzjoni ta' armonizzazzjoni rilevanti tal-Unjoni: Tagħmir ta' Protezzjoni Personali (PPE) - Regolament (UE) 2016/425
NL	is conform met de desbetreffende harmonisatiewetgeving van de Unie: Persoonlijke beschermingsmiddelen (PBM) - Regulation (EU) 2016/425
PL	przedmiot niniejszej deklaracji jest zgodny z odpowiednimi wymaganiami unijnego prawodawstwa harmonizacyjnego: Środków ochrony indywidualnej (ŚOI) - Rozporządzenie (UE) 2016/425
PT	está em conformidade com a legislação da União de harmonização aplicável: Equipamentos de Proteção Individual (EPI) - Regulamento (UE) 2016/425
RO	este în conformitate cu legislația relevantă de armonizare a Uniunii: Echipamentele Individuale de Protecție (EIP) - Regulamentul (UE) 2016/425
SK	je v súlade s príslušnými harmonizačnými právnymi predpismi Únie: Osobných Ochranných Prostriedkoch (OOP) - Nariadenie (EÚ) 2016/425
SL	je v skladu z ustrežno usklajevalno zakonodajo Unije: Osebná Varovalna Oprema (OVO) - Uredba (EU) 2016/425
FI	on asiaa koskevan unionin yhdenmukaistamislainsäädännön mukainen: Henkilönsuojaimista - Asetus (EU) 2016/425
SV	överensstämmer med den relevanta harmoniserade unionslagstiftningen: Personlig skyddsutrustning - Förordning (EU) 2016/425

EN	Applied harmonised standards or specifications	EN 149:2001+A1:2009
BG	Приложени хармонизирани стандарти или спецификации	
ES	Normas o especificaciones armonizadas aplicadas	
CS	Použité harmonizované normy nebo specifikace	
DA	Anvendte harmoniserede standarder eller specifikationer	
DE	Angewandte harmonisierte Normen oder Spezifikationen	
ET	Rakendatud harmoneeritud standardid või spetsifikatsioonid	
EL	Εφαρμοσμένα εναρμονισμένα πρότυπα ή προδιαγραφές	
FR	Normes ou spécifications harmonisées appliquées	
GA	Caighdeán nó sonraíochtaí comhchuibhithe curtha i bhfeidhm	
HR	Primijenjene usklađene norme ili specifikacije	
IT	Norme o specifiche armonizzate applicate	
LV	Piemērotie saskaņotie standarti vai specifikācijas	
LT	Taikyti darnieji standartai arba specifikacijos	
HU	Alkalmazott harmonizált szabványok vagy előírások	
MT	Standards jew speċifikazzjonijiet armonizzati applikati	
NL	Toegepaste geharmoniseerde normen of specificaties	
PL	Zastosowane zharmonizowane normy lub specyfikacje	
PT	Normas ou especificações harmonizadas aplicadas	
RO	Standarde sau specificații armonizate aplicate	
SK	Použité harmonizované normy alebo špecifikácie	
SL	Uporabljeni harmonizirani standardi ali specifikacije	
FI	Sovellettuja yhdenmukaistettuja standardeja tai eritelmiä	
SV	Tillämpade harmoniserade standarder eller specifikationer	

EU-Type Examination Notified Body	CCQS Certification Services Limited [Ireland] N.B. No. 2834
EU-Type Examination (Module B) Certificate Number	CE-PI-20200723-01-01-9I
Module D (NB Name and Number)	SGS Fimko Oy [Finland] N.B. No. 0598
Issued under sole responsibility of: Alpha Solway Limited Factory 1 Queensberry Street, Annan, Dumfriesshire, DG12 5BL.	
Economic Operator (EU): Globus EMEA Ltd , 51 Dawson St., Dublin, D02 AN25, Ireland	
	
Mr. J. Magniez Regulatory & Quality Manager 01/07/2026	

UK DECLARATION OF CONFORMITY

ACCORDING TO PPE REGULATION (EU) 2016/425



“ALPHA HX SERIES” - FILTERING HALF MASKS

[INC. MODEL(S): [HX-2, HXL-2, HX-2V, HXL-2V, HX-3, HXL-3, HX-3V, HXL-3V]

The manufacturer: Alpha Solway Limited
Factory 1, Queensberry Street, ANNAN,
Dumfriesshire, Scotland, DG12 5BL. United Kingdom.

Confirms conformity to: UK Regulation 2016/425 On PPE as brought into UK Law and amended

And the standard(s): EN 149:2001+A1:2009

Of the following PPE product(s):

“Alpha HX Series” - Filtering Half Masks - To Protect Against Particles.

Product Codes: HX-2 [FFP2 NR], HXL-2 [FFP2 NR], HX-2V [FFP2 NR], HXL-2V [FFP2 NR], HX-3 [FFP3 NR], HXL-3 [FFP3 NR],
HX-3V [FFP3 NR], HXL-3V [FFP3 NR]

The Approved Body **CCQS UK Limited [United Kingdom], [A.B. No. 1105]**

performed the UK Type-Examination, [Module B], and issued the UK Type-Examination Certificate:

CA-PU-20210428-01-01-9E

The PPE is subject to the conformity assessment procedure, conformity to type based on quality assurance of the production process, [Module D], under the surveillance of the Approved Body:

SGS United Kingdom Limited [United Kingdom], [A.B. No. 0120]

Signed for and on behalf of:

Alpha Solway Limited, Factory 1, Queensberry Street, ANNAN,
Dumfriesshire, Scotland, DG12 5BL. United Kingdom.

Name: Mr. J. Magniez

Function: Regulatory & Quality Manager

Date of issue: 01/07/2026