USER INFORMATION

AAG powder free nitril gloves 3.5 gram

21/04/2023

Product code: AAG powder free Nitrile gloves 3.5 gram
Product name: Powder free Nitrile gloves, blue, non-sterile
Available sizes: S, M, L, XL

1. EU Type-Examination

a) This product is classed as **Category III** Personal Protective Equipment (PPE)according to PPE Regulation (EU) 2016/425 and has been shown to comply with this Regulation through the Harmonised European Standards EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016.
b) Notified Body responsible for certification and Module B compliance is SATRA Technology Europe Limited (2777), Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland.
c) Notify Body responsible for internal production control plus supervised product checks at random intervals (Module C2) is SATRA Technology Europe Limited (2777), Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland.
d) The EU Declaration of Conformity is accessible at https://aag.world/shop/nitrile-powder-free-1135p.html

2. Marking

a) **Micro Organism Hazards Pictogram**: EN ISO 374-2:2019 Resistance to Penetration. No leak detected during air and water leak test. Minimum AQL is 1.5 or EN performance level 2; Additional information obtainable from the manufacturer.

Performance Level	AQL	Inspection Level
Level 3	<0.65	G1
Level 2	<1.5	G1
Level 1	<4.0	S4

b) **Micro Organism Hazards Pictogram**: EN ISO 374-5:2016 Protect against Bacteria, Fungi and Virus. No penetration of bacteriophages through the specimen and the following pictogram is applied.

ISO 374-5:2016

VIRUS

c) **Chemical Hazards Pictogram:** BS EN ISO 16523-1:2015+A1:2018; Additional information on chemical resistance obtainable from manufacturer.
EN ISO 374-1:2016+A1:2018 permeation levels are based on breakthrough times as follows:

Performance Level	0	1	2	3	4	5	6
Minimum breakthrough time (mins)	*	10	30	60	120	240	480

*Indicates that the glove falls below the minimum performance level as stated in EN ISO 374-1:2016 + A1:2018 for the given individual hazard.

This product complies with Type B requirements and the following pictogram shall be used with reference to clause 6.3 of ISO 374-1.

ISO 374-1/Type B

KTP

3) Performance and Limitation of Use

a) This product had been tested in accordance with EN ISO 374-5:2016.
Protection against bacteria and fungi - Pass
Protection against viruses - Pass
b) Gloves had been tested in accordance with BS EN ISO 16523-1:2015+A1:2018 resistance to permeation by chemicals and achieved the following performance levels:

Chemical	Performance Level
*4% Chlorhexidine Digluconate	6
40% Sodium Hydroxide (K)	6
10-13% Sodium Hypochlorite	6
50% Sulphuric Acid	6
10% Acetic acid	4
5% Ethidium Bromide	6
37% Formaldehyde (T)	3
65% Nitric Acid (M)	0
50% Glutaraldehyde	6

Chemical	Performance Level
0.1% Phenol	6
30% Hydrogen peroxide (P)	2
1.5% Methanol in water	6
70% Isopropanol	0
35% Ethanol	0
99% Acetic acid (N)	0
25% Ammonium Hydroxide (O)	0
3% Povidone Iodine	6
10% Sodium Percarbonate	6

The minimum observable permeation rate was 7ug/cm2/min.

i. This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
ii. The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical used in a mixture.
iii. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation.
iv. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.
v. Before usage, inspect the gloves for any defect or imperfections.

c) This product had been tested in accordance with BS EN ISO 374-4:2019 and achieved the following degradation results:

Chemical	Mean Degradation / %
4% Chlorhexidine Digluconate	19,0
40% Sodium Hydroxide (K)	-42,9
10-13% Sodium Hypochlorite	14,7
50% Sulphuric Acid	-20,5
10% Acetic acid	66,7
5% Ethidium Bromide	3,4
37% Formaldehyde (T)	5,0
65% Nitric Acid (M)	97,6
50% Glutaraldehyde	27,4

Chemical	Mean Degradation / %
0.1% Phenol	33,8
30% Hydrogen peroxide (P)	22,8
1.5% Methanol in water	21,9
70% Isopropanol	62,2
35% Ethanol	38,8
99% Acetic acid (N)	93,9
25% Ammonium Hydroxide (O)	-52,0
3% Povidone Iodine	33,7
10% Sodium Percarbonate	15,4

i. EN ISO 374-4:2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemicals.

d) This product provides protection against Bacteria, Fungi and Virus. The gloves had been tested in accordance with ISO 16604:2014 to meet the requirements of BS EN ISO 374-5:2016 for resistance to penetration by bloodborne pathogens-test method using Phi-X174 bacteriophage.
i. The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

e) The gloves were found to meet with the REACH annex XVII requirements for Polycyclic Aromatic Hydrocarbons (PAHs).
Where relevant, a list of the substances contained in the glove which are known to cause allergies, per listed in Annex G of EN ISO 21420:2020, shall be supplied on request.

f) Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, seek for medical advice immediately.

4) Gloves for Special Applications (EN 420:2003, Clause 5.1.3)

These gloves are designed to protect the hand surface from chemical splashes. Therefore, the length of the gloves is below EN requirements of total minimum glove length, and deems as 'Fit for Special Purpose'.

5) Product Instruction for Use

a) Usage – For Single Use only. If re-used, the risk of contamination and infection increases due to improper cleaning processes; and increased risk of holes and tear during re-use due to weakening of gloves by cleaning processes.
b) Sizing – Select the right size glove for your hand.
c) Donning – Hold glove by the bead with one hand. Align the glove thumb with your other hand thumb and slide your hand into the glove, one finger into each glove finger. Pull by the glove palm to a get a good fit. Don the other glove by the same procedure.
d) Inspection – Punctures or tears may occur after donning. Inspect each glove after donning, and immediately discontinue use if found damaged.
e) Doffing – Hold glove bead and pull toward the finger until the glove come off.
f) Disposal – Properly disposal of all used gloves. Follow your Institution's policies for disposal.

6) Handling and Storage

Store in a cool and dry place. Opened boxes should be kept away from fluorescent and sunlight. Gloves are packed in dispenser which is suitable for transport. Keep the gloves in the box when not in use.

7) Shelf life

The shelf life of product is 3 years from date of manufacture.

AA01-LF-AAGOBF-F-R2

Issued to:

AAG Aalborg Gummivarefabrik A/S
Sundsholmen 3
Norresundby
DK 9400
Denmark

Notified Body: 2777

SATRA customer number: P1343

EU Type-Examination Certificate

Certificate number: 2777/10015-07/E15-01

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product Reference	**Description**
Nitrile Powder Free 3.5g	Disposable blue powder free nitrile glove. Non-Sterile

Sizes: 6/7 (S) to 9/10 (XL)

Classification:

EN ISO 374-1: 2016+A1:2018 / Type B	**Level**	**EN ISO 374-4: 2019 Degradation %**
*4% Chlorhexidine Digluconate	6	19.0
40% Sodium Hydroxide (K)	6	-42.9
10-13% Sodium Hypochlorite	6	14.7
50% Sulphuric Acid	6	-20.5
10% Acetic Acid	4	66.7
5% Ethidium Bromide	6	3.4
37% Formaldehyde (T)	3	5.0
65% Nitric Acid (M)	0	97.6
50% Glutaraldehyde	6	27.4
0.1% Phenol	6	33.8
30% Hydrogen Peroxide (P)	2	22.8
1.5% Methanol in water	6	21.9
70% Isopropanol	0	62.2
35% Ethanol	0	38.8
99% Acetic Acid (N)	0	93.9
25% Ammonium Hydroxide (O)	0	-52.0
3% Povidone-iodine	6	33.7
10% Sodium Percarbonate	6	15.4
* Permeation rate 7µg/cm^2/min		
EN ISO 374-5: 2016		
Protection against Bacteria & Fungi	Pass	
Protection against viruses	Pass	

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: SPC0216113/1327/SMcD/RS, SPC0216113/1327, PRC0250570/1640/SPT, CHM0248297/1630/EN/E, CHM0248297/1630/EN/D/Issue 2, CHM0257198/1719/SMcD/A, CHM0257198/1719/SMcD/B, CHM0257198/1719/SMcD/C, CHM0257198/1719/SMcD/D, CHM0295960/2010/JH, CHM0303365/2041/LH, CHM0307207/2102/LC/A

Signed on behalf of SATRA: Kayleigh Aylward

Kayleigh Aylward

Date of issue: 21/04/2023
Expiry date: 03/02/2027

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.