



# CERTIFICATE OF REGISTRATION

*This is to Certify that*

## **DRA-OYSEN TRADERS CC**

Unit 18 Skyview Retail Park Randburg, Gauteng 2188, ZA, South Africa

*Operate a Quality Management System which complies  
with the requirement of*

### **ISO 13485:2016**

**(Medical Device – Quality Management System)**

*For the following Scope*

**"Manufacturing and Distribution of 3 Ply Flat Face Mask"**

Certificate Number :	200729062701
Initial Issue Date:	29 <sup>th</sup> Jul. 2020
Issue Date:	29 <sup>th</sup> Jul. 2020
Valid Until:	28 <sup>th</sup> Jul. 2021
1 <sup>st</sup> Surveillance Date:	29 <sup>th</sup> Jun. 2021
2 <sup>nd</sup> Surveillance Date:	29 <sup>th</sup> Jun. 2022
Revision:	00

  
 CEO  
 TNV Certification Pvt Ltd

***UAF is full member of International Accreditation Forum (IAF),***

*to check validity of this certificate  
please visit [uafaccreditation.org](http://uafaccreditation.org) or [www.tnvworld.com](http://www.tnvworld.com)*



United Accreditation Foundation Inc.  
400 York Centre Dr Ste 202 North  
Ft. Lauderdale, FL 33309  
United States Of America  
Registration No: 519941220007



MANAGEMENT SYSTEM CERTIFICATE

TNV Certification (Pty) Ltd, 175, 176 & 177, 2<sup>nd</sup> Floor, 5/5th Avenue, Lucknow, 2009 (India) | [info@tnvgroup.org](mailto:info@tnvgroup.org)  
 1. This certificate is issued to the organization, certifying its system as conforming with respective Management System Standards along with TNV's requirements.  
 2. This certificate remains the property of TNV Certification (Pty) Ltd. It should be returned upon request.  
 3. This certificate is not valid for any other purpose (for TNV and Accreditation Forum) if any change to meet the requirement shall be held liable for action.  
 4. This certificate is not free of liability. It is subject to audit and shall be valid only as given in TNV's official website ([www.tnvgroup.org](http://www.tnvgroup.org)) or write to [tnv@tnvgroup.org](mailto:tnv@tnvgroup.org).

# Declaration of Compliance

This Declaration of Compliance is hereby issued to the below named company.

**Applicable Directive(s):**  
93/42/EEC on Medical Devices Directive (MDD).

In accordance with the following applicable standards:  
EN 149:2001+A1:2009, EN 14683:2019+AC:2019.

## General Information

- Applicant** — DRA-OYSEN TRADERS CC  
Unit 18 Skyway Business Park Randburg,  
Gauteng 2188, ZA.
- Manufacturer** — Guardian Investment Holdings
- Product Description** — 3 Ply Mask
- Trade Name** — Guardian



Issued on 15-Jul-2020



**Certificate number: SA682771**

This certificate is valid from 15-Jul-2020 until 14-Jul-2021.

### This Certificate is issued under following conditions:

The product is declared by the applicant as complying with the applicable directives. UR has performed a review of the technical information of the product. The applicant is required to inform UR of any changes to its product design and technical documentation. The CE mark may be used by the applicant, for this product, under the sole responsibility of the applicant.

.....  
Certification Manager

## UNIVERSAL REGISTRARS

[www.universalregistrars.com](http://www.universalregistrars.com)

Level 18, 40 Bank Street,

Canary Wharf, London E14 5NR, UK.

Email ID: [info@universalregistrars.com](mailto:info@universalregistrars.com)

This certificate can be verified at the above URL.  
The certificate remains the property of Universal Registrars, to whom it must be returned on request. Lack of fulfillment of certification terms and conditions at all times, may render this certificate invalid.



The product liability rests with the manufacturer in accordance with their committed specifications and contractual obligations, including applicable standards. The CE mark shown above is for reference only, and does not indicate accreditation. Universal Registrars does not accept any liability arising out of this certificate.

PERFORMANCE TEST RESULTS AGAINST DEPARTMENT OF TRADE, INDUSTRY AND  
COMPETITION RECOMMENDED GUIDELINES FOR:

**FABRIC FACE MASK WITH FILTER**

VERSION 24<sup>th</sup> APRIL 2020



**DEFCONPROTEC**  
DEFENCE CONTRACTS AND PROTECTION TECHNOLOGIES

**PRODUCT DESCRIPTION**

**Blue/White Medical Design**

**3 Pleat Face Mask**

**Dra – Oysen Traders**

**CUSTOMER Dra Oysen Trading as Guardian**

**DATE 30<sup>th</sup> July 2020**



**DEFCONPROTEC**  
SPECIALISED PROTECTIVE EQUIPMENT

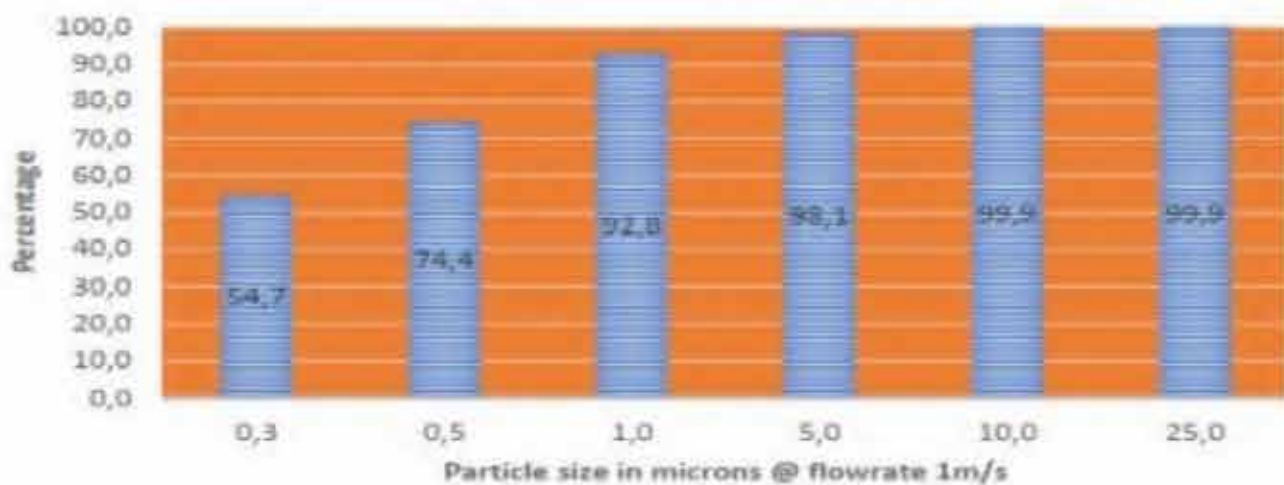


Test Characteristic	Method	Measurement	Results
Number of Layers	Visual	Visual	3
Mask Air Permeability	ASTM D737	cfm @ 125Pa	85
Breathability	SANS 6163	Grms/m <sup>2</sup> /24hrs	4159
Spray rating surface wetting	ISO 4920	Rating 1 - 5	4
Hydrostatic Head Water resistance	SANS 6310	mm Waterhead	325

Breathability and Permeability in line with DTIC Recommendations.

Sample displays high water repellency and good water resistance.

## PARTICLE HOLDOUT



### NOTES

The Dra -Oysen Guardian 3 pleat face mask comply with the requirements as stated in the DTIC Fabric Facemask Guidelines as published on 24<sup>th</sup> April 2020.

This is a disposable type face mask and not a re-usable face mask for public domain.

SIGNED