

Report No: (7420)190-0150 July 29, 2020

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Applicant: Puritas (Private) Limited

Address: No. 25, Foster Lane,

Colombo 10, Sri Lanka.

Sample Description: Sample Received As:

01 Pack. Of Face Mask Samples Submitted By The Client.

Sample Identified By The Client As:

Oxypura Care Face Mask

Label Detail: Colour: White

MFD: 20.03.2020 EXD: 20.03.2023

Batch No: CARE.FM-001MLA

Washing Instructions:

• Dip The Mask In Boiling Water For 3 To 5 Minutes And Sun Dry

(Repeat The Same For 14 Cycles)

• Do Not Expose The Mask To Dry Heat

Do Not Use Any Antiseptics, Detergents / Soap

• Do Not Rub, Squeeze

Do Not Machine Wash

Date Received: July 08, 2020

Date Out: July 29, 2020

Test Requested: Determination of a population of microorganisms on products.

(Microbial Cleanliness test (Bioburden) is performed on finished face masks) Test According to ISO 11737-1 :Sterilization of medical

devices-Microbiological methods –Part 1

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No. 570, Galle Road, Katubedda, Moratuwa, Sri Lanka

Tel: (9411) 2350111-115 (dedicated lines), Fax: (9411) 112622198 & 199

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Photo of the Submitted Sample



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TEST RESULTS

Test Article: Oxypura Care Face Mask

Test Method: Sterilization of medical devices-Microbiological methods –Part 1: Determination of a population of microorganisms on products. (Microbial Cleanliness test (Bioburden) is performed on finished face masks) (ISO 11737-1)

Weight Of The Mask Sample: 10.26 g

Type of microorganism	Facultative ,non-Fastidious, aerobic bacteria		Yeasts and moulds	
	cfu/mask	cfu/g	cfu/mask	cfu/g
RESULTS sample 1	15	1	12	1
RESULTS sample 2	12	1	9	1
RESULTS sample 3	12	1	9	1
RESULTS sample 4	15	1	12	1
RESULTS sample 5	18	2	15	1
Microbial cleanliness (Average results)	14	1	11	1
Microbial cleanliness cfu/g	02			
Requirement** for Medical face masks (Type Ia, Type II, Type IIR) cfu/g	≤30			

Requirement** for medical face masks as per BS EN 14683:2019

*Sample Item Portion (SIP) is calculated on the Basis of Mass of the tested Face Mask Removal Technique: Shaken for 5 min at 250 rpm.

NOTE

<03– Agar plate contains no colonies cfu/g - Colony Forming Units per gram

Comment: Sample was washed as per washing instructions given by vendor before testing

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Contact information for this report (Technical and General Inquiries and Feedback)

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EXECUTIVE QHSE		

REVIEWED BY: KASHMI JAYATHISSA

BUREAU VERITAS CONSUMER PRODUCTS SERVICES LANKA (PVT) LTD.

AUTHORIZED SIGNATORY

APPROVED BY:

RUWINI AMARASINGHE SENIOR EXECUTIVE -MICROBIOLOGY LABORATORY

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CPS CONDITIONS OF SERVICE

The party that submits a completed service request form to Company or signs a quotation issued by the Company for its performance of services ("Services") is the "Client" under these Conditions of Service. The entity within the Bureau Veritas Consumer Products Services division accepting the service request form and issuing the Report documenting the results of those Services is the "Company" under these Conditions of Service. Company and Client are, together, the "Parties" and each is a "Party". A request for Services constitutes a legally binding agreement on both Parties when such a request is accepted by the Company ("Agreement") under the following terms and conditions (collectively, "Conditions"):

- 1. Services. (a) The completion of the Services shall be evidenced by the Company's issuing to Client a written report setting forth the results of the Services based upon the properly accepted request, applicable protocols, written information, and where applicable, the product sample provided by Client to Company ("Report"). Company may delegate/assign the performance of all or a portion of the Services to an affiliate of Company or to an agent or subcontractor. Client shall provide to Company on a timely basis, all documents and information necessary to enable Company to properly perform the Services. Company may, in its sole discretion, dispose of product samples furnished to Company for the Services that were not destroyed in the course of performance of the Services. (b) Client represents and warrants to Company that (i) each product sample is not submitted in violation of a third party's intellectual property rights; (ii) Client will not use and rely upon Company's Report for any product whose properties differ from the sample(s) upon which the Report is based; and (iii) any goods subject to inspection will be completely prepared for the type of inspection booked for the specified date, and (c) Client accepts sole responsibility and liability for the accuracy of documents submitted to government or other regulatory bodies, including certificates of compliance required under the US Consumer Product Safety Improvement Act and EU requirements under REACH regulations. Client's responsibility and liability for accuracy shall apply even where Company has provided assistance to Client in preparation of such documentation.
- 2. Report. (a) The Report shall (i) constitute the sole deliverable for the Services, (ii) relate solely to the facts and circumstances as observed and recorded by Company at the time of performance of the Services within the limits of written informations received from Client; Company shall have no obligation to update the Report after its issuance. Where the Services include testing or inspection: (i) the Report will set forth the findings of Company solely with respect to the product samples identified therein and (ii) the results set forth in the Report are not to be construed as indicative or representative of the quality or characteristics of the lot from which a product sample was taken for Company's performance of Services. (b) The Report is insued solely by Company, is intended for the exclusive use of Client and its affiliates and, except as required by a regulatory body, shall not be published, used for advertising purposes, copied or replicated for distribution or publicly disclosed without Company's prior written consent. Company's prior most responsible for any third party's interpretation of the Report. (c) Client shall not request a Report for purposes of litigation, nor shall it list Company, its affiliates or employees as an expert in any proceeding without Company's prior written consent. It Client anticipates producing or otherwise using the Report in any legal proceedings, it shall so notify Company prior to submitting the Report in such proceeding.
- 3. Representations and Warranties. (a) Company undertakes due care and ordinary skill in the performance of its Services. (b) Client agrees that Company is neither an insurer nor a guarantor and does not take the place of Client or the third parties that it retains, including designers, manufacturers, agents, buyers, distributors, and transportation or shipping companies; Company desclaims all liability in such capacities. Client understands that, if it seeks to protect itself from claims of loss, damage or injury, it should obtain appropriate insurance. (c) Company does not warrant or guarantee Client's products, and Company's Report does not represent a warranty of merchantability, a warranty of fitness for a particular purpose, or any other warranty or guarantee.
- 4. Payment. Payment in full shall be due 30 days after the date of invoice, falling which Company may revoke any credit extended to Client. Client shall reimburse Company for (i) interest on overdue amounts from the due date until paid at an interest rate of 1.5% per month and (ii) any other costs Company incurs in collecting past due amounts, including court, attorneys and collection agencies' fees.
- 5. Intellectual Property. The names, service marks, trademarks and copyrights of Company and its affiliates (collectively, the "Marks") are and remain the sole property of Company and shall not be used by Client. Client shall not contest the validity of the Marks or take any action that might impair the value or goodwill associated with the Marks or the image or reputation of Company or its affiliates. Client understands that any information or samples submitted to Company is a license for Company to use the same in the performance of Services.
- 6. Relationship. (a) Nothing herein creates a partnership, agency or joint venture between the Parties. (b) The failure to require strict observance or performance of any provision of these Conditions shall not be construed to be a waiver of a Party's right to later require strict observance and performance of the same. If any provision of these Conditions is held to be invalid or unenforceable, such invalidity shall not invalidate the remainder of the Conditions. (c) For a period of two years after the commencement of this Agreement, Client shall not directly or indirectly try to solicit for employment any of Company's employees.
- 7. INDEMNITY. CLIENT SHALL HOLD HARMLESS AND INDEMNIFY COMPANY, ITS AFFILIATES, AND THEIR RESPECTIVE DIRECTORS, OFFICERS, EMPLOYEES, AGENTS AND SUBCONTRACTORS AGAINST ALL THIRD-PARTY CLAIMS FOR LOSS, DAMAGE, INJURY, DEATH, OR EXPENSE OF WHATEVER NATURE, INCLUDING BUT NOT LIMITED TO CLAIMS ARISING FROM OR RELATING TO (I) THE PERFORMANCE OF ANY SERVICES BY COMPANY, (II) THE SALE, RESALE, MANUFACTURE, DISTRIBUTION OR USE OF ANY OF CLIENT'S GOODS OR (III) BREACH OF CLIENT'S OBLIGATIONS OR WARRANTIES HEREIN.
- 8. LIMITATIONS OF LIABILITY. (A) COMPANY SHALL NOT BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL OR SPECIAL LOSS IN CONNECTION WITH THE REPORT, THE PRODUCT FOR WHICH SERVICES WERE PERFORMED, OR THE SERVICES PROVIDED BY COMPANY HEREUNDER. COMPANY SHALL NOT BE LIABLE FOR ANY LOSS OR DAMAGE WHATSOEVER RESULTING FROM ANY DELAY IN THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER OR FROM THE FAILURE OF COMPANY TO PROVIDE ITS SERVICES WITHIN ANY TIME PERIOD FOR COMPLETION ESTIMATED BY COMPANY, REGARDLESS OF THE CAUSE OF THE DELAY OR FAILURE. (B) THE ENTIRE FINANCIAL AND LEGAL LIABILITY OF COMPANY IN RESPECT OF ANY CLAIM FOR LOSS, INDEMNITY, CONTRIBUTION OR DAMAGE OF WHATEVER NATURE OR HOWSDEVER ARISING, SHALL NOT EXCEED AN AMOUNT EQUAL TO FIVE (5) TIMES THE AMOUNT OF FEES PAID TO COMPANY FOR THE SPECIFIC SERVICES WHICH GAVE RISE TO SUCH CLAIM.
- 9. Force Majeure. If any event of force majeure or any event outside the control of Company occurs, Company may immediately cancel or suspend its performance hereunder without incurring any liability whatsoever to Client.
- 10. Governing Law. These Conditions shall be governed by the laws of the country as follows: for Services performed in (i) the Americas: the laws of New York, (ii) Asia Pacific, South Asia, Middle East and Africa: the laws of Hong Kong (except for China where PRC laws govern), and (iii) Europe: the laws of England.
- 11. Dispute Resolution. (a) If Client desires to assert a claim relating to the Services, it must submit the same to Company in writing setting forth with particularity the basis for such claim within 90 days from discovery of the claim and not more than six months after the date of issuance of the Report. Client waives any and all claims without limitation that it does not submit within such time periods, (b) If a dispute arises under this Agreement, the Parties shall first attempt good faith negotiations, failing which, the Parties (i) agree that the courts of the country of governing law shall have exclusive jurisdiction to settle any such dispute related to this Agreement and (ii) irrevocably waive their right to trial by jury in any such action or proceeding.
- 12. These Conditions, the applicable order form and/or quotation and the Report represent the entire understanding of the Parties on the subject matter hereof, and no modification is binding unless in writing. Any of Client's terms and conditions attached to, enclosed with or referred to in any order form, purchase order or other document shall not apply.

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END OF THE REPORT.