Test of "SPLASH RESISTANCE" in agreement with the guidelines of ISO 22609:2004(E). Client KB MEDICA (KBL Group), mask code "belg".

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1. Order Reference

TPM_2020_1051_BIO9s

2. Purpose

"SPLASH RESISTANCE" analysis: evaluation of the resistance of the device to the penetration of a certain volume of synthetic blood by high-speed impact between liquid and device for a short period of time (1 second). The analysis is carried out following the guidelines of ISO 22609:2004(E).

2.1 Specimen

KB MEDICA (KBL Group), supplied to the laboratory 32 complete face masks, from the production batch "**1**". Mask code **"belg"**, mask denomination "**Chin number 1**".

2.2 Sample preparation

Samples have been tested without any modification in their geometry, whatsoever. The sample is pre-conditioned in a climatic chamber at a temperature of 21 ° C and relative humidity of 85% for 4 hours before the analysis. The measurement is made within 1 minute of removal from the climatic chamber.

3. Materials & Methods

3.1 Materials

- Demineralized H20 0.055 µS / cm
- Triton X 100 X Sigma-Aldrich cod. T8787; batch MKBR5267V
- Direct RED 80 sigma aldrich cod. 365548; batch MKBB6842V

Synthetic blood is made from a 15 mg / L solution of Triton X 100 and a Direct RED 80 red color 200 mg / L in demineralized water.

3.2 Instrumentation

- "Flower 340" climatic chamber Serial Number: 011TT29. Performance certificate valid until September 2020.
- "Winkratos 5.00" software.
- 3D-Bioplotter ENVISIONTEC, serial number ETB41507M056, (MS2_066)

3.3 Experimental method

The analysis is based on the visual observation of the sample subjected to a squirt of synthetic blood at high speed to simulate an accidental leakage of the patient's blood in the surgical site. The sample is mounted on a special support perpendicular to the direction of the liquid flow. The squirt of synthetic blood, whose speed and quantity are comparable to the excision of a large artery, takes place by pneumatic impulse through a syringe containing synthetic blood, a needle of defined section and length and a piston on which electronically regulated pressure is exerted via software. The quantity of liquid dispensed is 2.0 ml. The observation is done visually and through the use of a tissue paper, noting that the liquid does not pass through the mask or does not wet the inside after 10 seconds from performing the test. Synthetic blood is prepared using a solution of Triton X 100 in order to have a surface tension of 0.042 N / m, comparable to that of whole blood.

3.4 Experimental conditions

The experimental parameters for the test have been set as indicated below:

Sample-cannula distance	Cannula internal diameter	Cannula length	Pressure	Pulse duration
30 cm	0.84 mm	12.7 mm	21 kPa	0.7 s
30 cm	0.84 mm	12.7 mm	16 kPa	0.9 s

3.5 Acceptance criterion

The test is carried out according to ISO 22609:2004 on the samples available at the maximum designated pressure of 21kPa. In case of permeation to synthetic blood, the test is carried out at a pressure of 16kPa, corresponding to the minimum pressure allowed by UNI EN 14683:2019 for surgical masks. To have an AQL of 4% the test is considered approved if the number of samples that exceed the resistance to penetration of liquid are at least 29.

4. Results

The masks with sample code **"belg",** mask denomination **"Chin number 1"**, have been subjected to pre-treatment and splash resistance test. Figure 1 shows a representative image of the internal and external part of a sample template.

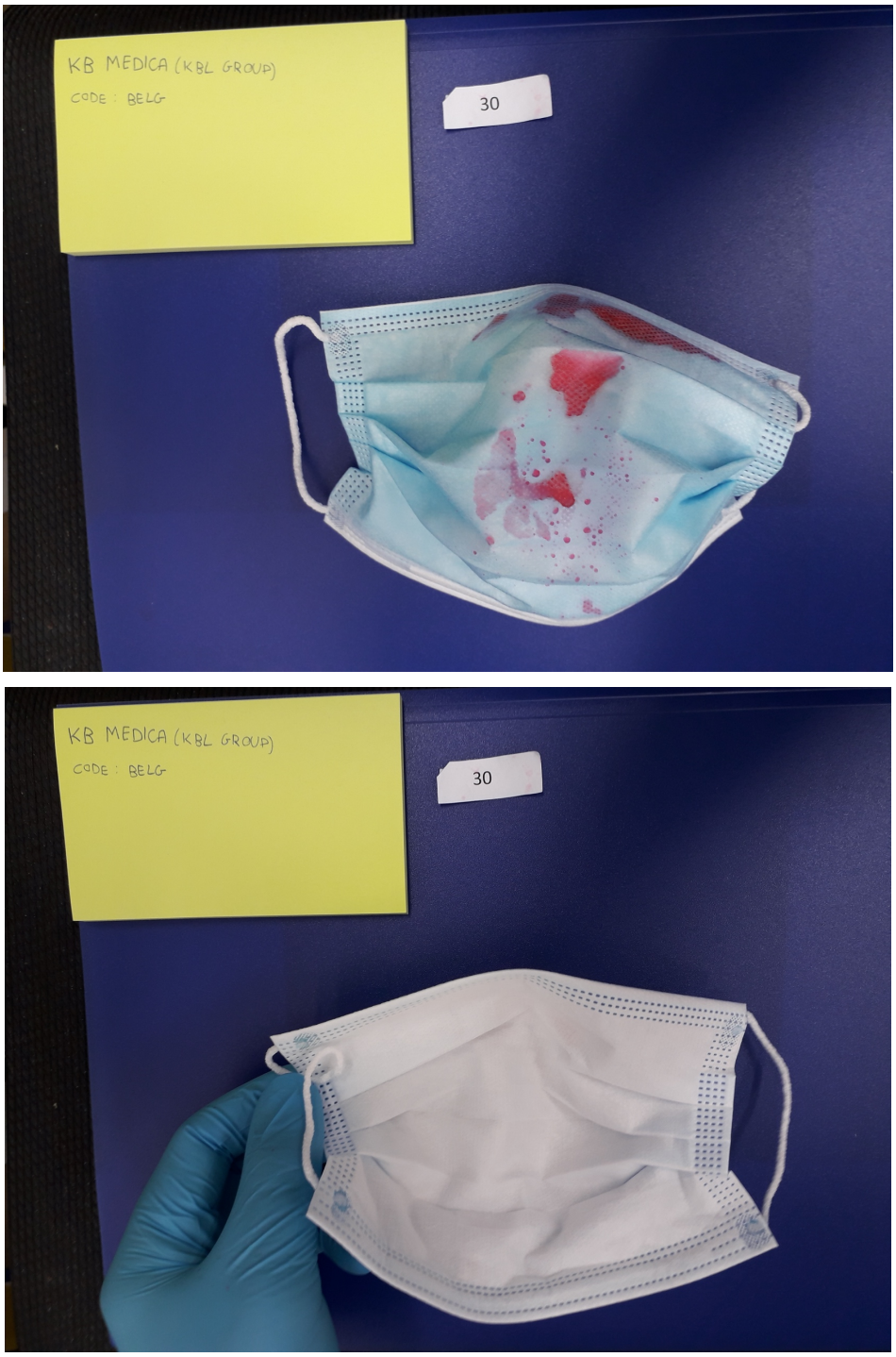

Figure 1: External side at the top and the internal side at the bottom, after splash resistance test

Of the 32 masks tested, none showed the permeation of synthetic blood in the internal part of the mask within 10 seconds, and also in greater times, from the application of the squirt of liquid at the pressure of 21kPa.

5. Conclusions

The tests carried out indicate that the materials used may be suitable for the construction of a mask classifiable as IIR.