

安吉鑫沅进出口有限公司

ANJI SPENQ INDUSTRIAL CO., LTD.

地址: 浙江省安吉塘浦经济开发区 电话: +86 572 5882803 传真: +86 572 5882115

PRODUCT STATEMENT

Date: 2021/04/15

LISMEDFARM S.R.L. &
TO WHOM IT MAY CONCERN

Hereby company **Anji SPENQ Industrial Co., Ltd.**, a manufacturer of disposable medical devices based in **F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China**, states that our products KN95/FFP2 Respirator (SJ12) and Medical face mask (SJ05) comply with the requirements of the tender organized on 22.04.2021 by the Moldovan procurement agency in health CAPCS as following:

1. KN95/FFP2 Respirator (SJ12) complies with the following requirements:

a. Medical device with filtering capabilities without valve.

b. Capacity level at least 94%.

Comment: Our product has filtration level at least 95% according to GB2626-2019 standard.

c. Good breathability with fixed form and doesn't stick to the mouth.

Comment: The cone-shape of the respirator allows it to not stick to the user's mouth.

d. Single use only.

e. With elastic bands on the head, flexible, soft.

Comment: The respirator bands fix to the user's ears with soft and flexible bands that do not rub against them, allowing for comfortable user experience.

f. Complies with international standards recommended by WHO: Europe (EN 149) or USA (NIOSH CFR PART 84) or their equivalent with the presentation of confirmatory documents.

Comment: Our product complies with standard GB2626-2019 Chinese standard which is confirmed by the COA. This standard is recommended by WHO and is equivalent to EN149 & NIOSH CFR PART 84. WHO recommendation with proof; *COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies (07 August 2020) on page 20*

https://www.who.int/docs/default-source/medical-devices/technical-specs-ppe-covid19.pdf?sfvrsn=f76a2552_2

2. Medical face mask (SJ05) complies with the following requirements:

a. Non-woven material, three layers, with folds. Does not contain fiber glass and latex. Hypoallergenic. Fixing with elastic. Allow effortless breathing.

b. Clearly identify the internal and external part of the mask

Comment: The internal and external parts are identified by the colour

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of the material and the placement of the elastic band. Any professional health worker should be able to differentiate between the two sides and thus to them it is clearly identifiable.

- c. Bacteria filtration (BFE) min 98%, confirmed by certificate and / or test report.

Comment: Our product has filtration level at least 98% according to EN14683:2019 standard.

- d. Adaptable to face shape, with metal nose bar. Packing up to 100pcs, non-sterile.

Comment: The packing is 50pc/box

- e. Medical masks must comply with WHO recommended standards, namely confirmation of possession of ASTM F2100, or EN 14683, or an equivalent standard.

Comment: Our medical face mask complies with EN 14683:2019 which is confirmed by the test report

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Best regards,

Davy Jiang

Senior Sales Manager (I Class)

