# CERTIFICATE of CONFORMITY STERILE FILTER ELEMENT

Manufacturer: Dongguan Chuangzhi Machinery Co., Ltd.

Product is guaranteed to meet the following specifications: ISO-8573.1

Product number: Sterile Filter element: 1030CJ

Lot number: 20231212

Date: 2023.12.12

Sterile filter elements are manufactured to compatible with the requirements of sterile degree in compressed air and gas feed and these are confirmed to be sterilized as per standards EN 285, EN ISO 17665-1 a maximum temperature of 138°C.

### **Material Of Filter Element Construction:**

Filter material: Imported PTFE membrane

Production process: Twine Dimensions (mm): 42\*54

Outer frame: 304 stainless steel

Center column: 304 stainless steel Internal

Upper and lower cover material: 304 stainless steel

Maximum working pressure: 6.5Mpa

Operating pressure: **6Mpa**O-ring material: EPDM

Typical gas flow: **Q>=0.5M³/min** 

Filtration precision: **0.01μm** 

Particle Filtration Efficiency: **99.999%**Oil mist filtration efficiency: **0.01mg/m**<sup>3</sup>

Maximum allowable differential pressure: 0.14MPa

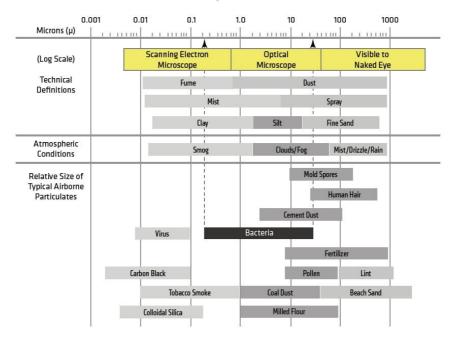
Pressure loss (kgf/cm<sup>2</sup>): <=0.06

Sealant: white silicone compound, selected for resistance to high temperature,

composition in accordance with F.D.A. recommendations

Maximum operating temperature: <100 ° C

## **Size Comparison Chart**





It is User's responsibility to ensure that a suitable process for inhibiting growth of trapped bacteria and virus is respected. It is therefore recommended to sterilize the filter prior commencement of each sequence of aseptic duty. These elements are capable of withstanding sterilization phases of 20 minutes in autoclave at 121°C (50 steps maximum executable). For "in situ" steam sterilization, conventional steam condition for this purpose should be balanced across filter element with a small flow orifice directed from outside to in. After steam sterilization, the element should be allowed to flash dry before the process gas is turned on.

### FILTER ELEMENT SPECIFICATION:

Filter grade  $0.01 \mu$  Max. sterilizing temperature  $138^{\circ}\text{C}$ 

Sterilizing temperature 121°C @ timing 20'as per ENISO 17665-1 Sterilizing temperature B 132°C @ timing 5' as per ENISO 17665-1

Initial pressure drop, clean and dry 150 mbar
Change filter element 400 mbar
Flowing Out To In

## **IMPORTANT NOTE:**

- Before replacing the filter element, make sure that the O-ring and the housing are clean.
- Once differential pressure limits or working hours are reached, filter element must be replaced.
- Only competent Personnel is allowed to install, perform maintenance, or replace filter elements.
- It's forbidden to move or to replace any filter element from the filter housing under pressure.

Dongguan Chuangzhi Machinery Co., Ltd.
Quality Inspection Department