



## Quality Risks During Manufacturing

Quality control starts at the beginning of the manufacturing process with the analysis of raw materials and continues through the final product release. During the production workflow, chemicals may leave residues on masks, such as degradation reagents (Di-tert-butyl peroxide or DTBP), disinfectants (ethylene oxide), dyeing agents, formaldehyde, and heavy metals. It is the manufacturers' responsibility to meet established health, safety and quality standards and to test for contamination and potential risks and liabilities.

The material most used to make surgical face masks is polypropylene, but masks can also be made of polystyrene, polycarbonate, polyethylene, or polyester. Masks shall not be made from recycled materials and/or materials with high toxicity, potential or known carcinogens, nor should materials be used that can cause skin irritation or other adverse reactions.

## Testing Solutions

We offer a large portfolio of analytical testing solutions that provide manufacturers with the capability to run tests to confirm the quality of their products.

### Example of the protective layers of surgical and medical face masks

**Outmost layer:** Spun-bonded non-woven polypropylene. (waterproof and bacteriostatic layer)



**Middle layer:** PP melt-blown superfine fiber. (filtration layer)

**Inner layer:** Non-woven fabric (water-absorbing and skin-friendly layer)

| TEST ITEMS          | RELATED STANDARDS   | ELIGIBILITY CRITERIA       | DETECTION METHOD   | PERKINELMER SOLUTION  |
|---------------------|---|----------------------------|--|---|
| Ethylene Oxide (EO) | CNS 14393-7, ISO 10993-7<br>Biological Evaluation of Medical Materials    | 1 ppm                      | Gas Chromatography, Headspace  | Clarus® Series GC, TurboMatrix® HS  |
| Azo Dye             | CNS 15290 Textile Safety Code, ISO 14362                                  | <30 ppm                    | Gas Chromatography<br>Mass Spectrometer Analysis   | Clarus® SQ8 GCMS  |
| Formaldehyde        | CNS15580-1Determination of formaldehyde in textiles, ISO 14184 -1         | <75 ppm                    | Analysis of UV/Visible Spectrometer  | LAMBDA® 365   |
| Flammability        | ASTM F2100-19, See European Medical Directive (2007/47/EC, MDD 93/42/EEC) | Class 1<br>(≥ 3.5 seconds) | Thermogravimetric Analysis (TGA)   | TGA 4000 System   |
| Biocompatibility    | ISO 10993   |                            | <b>For Volatile Organic Compounds:</b><br>Gas Chromatography,Headspace,<br>Gas Chromatography,<br>Mass Spectrometer Analysis<br><b>For Heavy Metals:</b> Atomic Spectroscopy | <b>For Volatile Organic Compounds:</b><br>Clarus® Series GC, TurboMatrix® HS<br>Clarus® SQ8 GCMS<br><b>For Heavy Metals:</b> Avio™ Series ICP-OES,<br>NexION™ Series ICP-MS |

## Determination of Heavy Metals in Materials Such As Masks

| TEST ITEMS   | GB/T 18885-2009 |               | GB 17593.1 AAS METHOD |       | GB 17593.2 ICP-OES METHOD | ICP-MS METHOD | PERKINELMER SOLUTION                       |
|--------------|-----------------|---------------|-----------------------|-------|---------------------------|---------------|--|
|              | RESIDUE         | LIMIT (mg/Kg) | GRAPHITE              | FLAME |                           |               |  |
| Heavy Metals | Antimony (Sb)   | 30            |                       | ✓     | ✓                         | ✓             | PinAAcle™ Series AAS, Avio™ Series ICP-OES |
|              | Arsenic (AS)    | 1.0           |                       |       | ✓                         | ✓             | NexION™ Series ICP-MS                      |
|              | Lead (Pb)       | 1.0           | ✓                     |       | ✓                         | ✓             |  |
|              | Cadmium (Cd)    | 0.1           | ✓                     |       | ✓                         | ✓             |  |
|              | Chromium (Cr)   | 2.0           | ✓                     |       | ✓                         | ✓             |  |
|              | Cobalt (Co)     | 4.0           | ✓                     |       | ✓                         | ✓             |  |
|              | Copper (Cu)     | 50            |                       |       | ✓                         | ✓             |  |
|              | Nickel (Ni)     | 4.0           | ✓                     |       | ✓                         | ✓             |  |
| Mercury (Hg) | 0.02            |               |                       |       | ✓                         |               |  |

**You have questions and like to learn more from our experts?**

[Contact your local PerkinElmer representative to explore your options and discuss your needs.](#)

PerkinElmer, Inc.  
940 Winter Street  
Waltham, MA 02451 USA  
P: (800) 762-4000 or  
(+1) 203-925-4602  
[www.perkinelmer.com](http://www.perkinelmer.com)



For a complete listing of our global offices, visit [www.perkinelmer.com/ContactUs](http://www.perkinelmer.com/ContactUs)

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