

Regulatory Standards Relevant to ViriMASK™

We are making available the following links to current international regulations & standards for personal protective equipment. By clicking on one of these links, you are leaving the ViriMASK™ internet site. Virimask, Ltd. make no claims of privacy, or data usage, and has no control over the content or other internet sites. The links to these other internet sites are only provided for your convenience.

- Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC <https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=39204&no=1>
- Conformity assessment procedure: Category I: internal production control (module A) set out in Annex IV [ec.europa.eu › translations › renditions › native](https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=39204&no=1)
- Manufacturer ISO 13485:2016 QMS certificate <https://www.iso.org/standard/59752.html>
- Biocompatibility statement (ISO 10993) Cytotoxicity <https://www.fda.gov/media/85865/download>
- Microbial Cleanliness ISO 11737-1 <https://www.iso.org/obp/ui/#iso:std:iso:11737:-1:ed-3:v1:en>
- Bacterial Filtration Efficiency % ASTM F2101, EN 14683 <https://www.astm.org/Standards/F2101.htm>
- Respiratory Precertification Tests - NIOSH/EN149 <https://www.nelsonlabs.com/testing/respirator-pre-certification-tests-niosh/>