**Surgical Face Masks - For Clips Project**

Surgical masks are Class 1 Medical Device.

“masks for the protection of the user (e.g. from the environment) are not medical devices, however, surgical masks (for use in an operating theatre) are medical devices as they are intended to protect the patient rather than the user”

Reference: <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/284505/Borderlines_with_medical_devices.pdf>

**Standard for surgical masks: Medical Face Masks - BS EN 14683:2019**

“The main intended use of medical face masks is to protect the patient from infective agents and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.”

“Type I medical face masks are used for patients in order to reduce the risk of the spread of infections, particularly in epidemic or pandemic situations. Type II masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements.”

“The level of efficiency offered by a mask depends on a number of factors such as the filtration efficiency, quality of the material and the **fit of the mask** on the wearer’s face. Different designs are suited for different applications and the careful choice of mask is therefore important in order to achieve the desired result.”

“Due to the fact that used masks are considered highly contaminated, it is essential that:

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| — | **the body of the mask is not touched by the fingers/hands of the wearer;”** |
| — | a mask is worn covering the nose and mouth of the wearer, at no time a mask is hanging around the neck of the wearer” |

* Use of the clip must not reduce Particle filtration, Bacterial Filtration, Breathability or blood fluid penetration