Requirements Specification

# General Device Description & Intended Purpose

The product is a disposable cardboard attachment which sits on the back of the user’s head and is used to secure the elastic ear loops of disposable surgical masks.

It is intended to be used:

* To improve security of disposable Type IIR surgical masks with elastic ear loops against face compared to having no extra securement method
* To be more comfortable than the current recommended securement method (knots tied in the ear loops)

Type IIR surgical masks are a Class 1 medical device, and as such the face mask clip is an accessory to a medical device.

# Specifications for Product

## User Requirements

* The clip should deliver increased ear comfort compared to current best practice for surgical masks with ear loops (knotted ear loops)
* The clip should enable surgical masks with ear loops to be tightened such that they fit closely to the face
* Clip should be manufacturable at scale: projected best case 88635 surgical masks used in April (worst case: 354540)
* The clip is single use so disposable alongside face mask
* Clip must allow for different head sizes and be adjustable for tightness and comfort
* The edges and corners should not be sharp, such that they could rip gloves or cause injury
* Robust in expected usage conditions
* The clip must be suitable for a patient to wear whilst lying in bed
* There should be no increased risk of COVID infection due to use of the clip compared to current best practice
  1. Specification

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| **User Requirement** | **Specification** |
| The clip should deliver increased ear comfort compared to current best practice for surgical masks with ear loops (knotted ear loops) | Design must prevent the elastic ear loops being tightened against the user’s ears |
| The clip should enable surgical masks with ear loops to be tightened such that they fit closely to the face | The clip should enable surgical masks with ear loops to be tightened such that they fit closely to the face, such that the fit is as effective (or better) as with knotted ear loops |
| Clip should be manufacturable at scale: projected best case 88635 surgical masks used in April (worst case: 354540) | Design suitable for mass production of at least 10,000 units per day |
| The clip is single use so disposable alongside face mask | < 10p per item |
| Suitable for incineration |
| Minimum material per clip |
| Clip must allow for different head sizes and be adjustable for tightness and comfort | Design should enable users to adjust tightness |
| The edges and corners should not be sharp, such that they could rip gloves or cause injury | No sharp corners/edges |
| Robust in expected usage conditions | The clip must not break for a maximum usage duration of 4 hrs |
| The clip must be suitable for a patient to wear whilst lying in bed | Clip profile flat against head, no protrusions |
| There should be no increased risk of COVID infection due to use of the clip compared to current best practice | Must be provided clean (but not sterile, does NOT need to be sterilisable or resistant to cleaning products) |
| Should not incur increased handling of ‘dirty’ PPE or hair/face/head when doffing |
| The clip should not impact the usage or security of other PPE |

**Monitoring compliance with and the effectiveness of this document**

This process forms part of a quality system accredited to International Standard EN ISO 9001:2015, EN ISO 13485:2016 and BS 70000:2017. The effectiveness of the process will be monitored in accordance with the methods given in the Quality Manual (CE-QS-QAM-4).

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