Clinical Evaluation Report

1. Product

- Name: *Surgical Ear-loop/Tie-on Face Masks Type IIR*
- Version: *0.0*
- MD Class: *Class I*

The classification is based on the following criteria:

- According to the EU Regulation 2017/745 (MDR) Annex VIII Rules: *<Rule 1.0>*.

2. Scope of the Clinical Evaluation

This document is applicable for *Surgical Ear-loop/ Tie-on Face Masks Type IIR. The evaluation is applied for the intended use of the surgical face-masks.*

3. Device

3.1 Device Description

The disposable 2REL B and 2RTO G facemasks are constructed of a three-layer filtration system of nonwoven soft and breathable fiber for effective protection. The masks feature extra soft and comfortable elastic ear-loops that will not apply pressure to the ears during use and have an adjustable nose bridge strip. The disposable masks are ideal for one-time use only. It is intended to limit the transmission of infectious agents and body fluids by patient and personnel during medical procedures and other facilities with similar requirements. The surgical mask has a suitable microbial barrier. The surgical facemasks 2REL B are intended for use by healthcare professionals in order to reduce the risk of the spread of infections. See Chapter 1 in Technical file.

3.2 Clinical Benefits, Outcome Parameters

1. Surgical facemasks are used to prevent the direct passage of pathogens, microorganisms, particles and other physical barriers. Disposable surgical mask is self-absorption filter mask; the principle of work is to make the air containing harmful substances pass through the filter material of the mask to be inhaled or exhaled. It resists splashes too.

2. BFE (Bacterial Filtration Efficiency) of the facemask is > 95 %.

3.3 Clinical Safety and Acceptability of Benefit-Risk-Ratio

See RMS (Risk Management File) attached.

4. Clinical Data from Literature

Surgeons and nurses performing clean surgery wear disposable face masks. The purpose of face masks is thought to be two-fold: to prevent the passage of germs from the surgeon's nose and mouth into the patient's wound and to protect the surgeon's face from sprays and splashes from the patient. Face masks are thought to make wound infections after surgery less likely. However, incorrectly worn masks may increase the likelihood of the wound getting contaminated with germs.

Surgical face masks were originally developed to contain and filter droplets containing microorganisms expelled from the mouth and nasopharynx during surgery. They were introduced around a century ago as a method of protecting patients from the risk of surgical wound infections (Belkin 1997). The costs incurred when a patient contracts a surgical wound infection are considerable in financial as well as social terms. It has been estimated that each patient with a surgical wound infection requires an additional hospital stay of 6.5 days and that hospital costs are doubled (Plowman 2000). When extrapolated to all acute hospitals in England, it is estimated that the annual cost nationally is almost GBP 1 billion.

The primary purpose of a surgical mask is to provide protection for the patient from the surgical team. Masks have also been advocated as a barrier to protect the surgical team from the patient (Garner 1996; Weber 1993).

Surgical face masks are worn in the perioperative period for two reasons: to protect the patient and also the wearer. Protecting the patient is of paramount importance, with surgical site infections (SSI) increasing the length of hospital stay by an average of 6.5 days (Plowman, 2000) resulting in costs to the NHS in England of an estimated £1 billion (Vincent and Edwards, 2016). SSIs have been shown to significantly increase mortality as well as morbidity (Coello et al., 2005). Second, appropriate face mask application provides protection for theatre staff themselves, given that blood or body fluid splash is present in up to 45% of operations (Davies et al., 2007) and that there is risk of disease transmission; in the case of HIV, there is a 0.1% risk of transmission with mucus membrane exposure to HIV-infected blood.

Facemasks are used nowadays by public in order to prevent infections transmission.

5. Conclusions

However, there is no clear evidence states that surgical facemasks reduce the SSI, there are many evidences state that facemasks prevent and reduce the probability of infections and viruses' transmission.

6. Date of the Next Clinical Evaluation

The review date is on 11/10/2022.

7. References

- The Impact of Community Masking on COVID-19: ACluster-Randomized Trial in Bangladesh, Jason Abaluck, August 31, 2021, *https://www.poverty-action.org/sites/default/files/publications/Mask_RCT___Symptomatic_Seropositivity_083121.pdf*.

- *A rapid review of the use of face mask in preventing the spread of COVID-19, MaryAbboah-Offeia, November 2021,* *https://reader.elsevier.com/reader/sd/pii/S2666142X20300126?token=6A88EB49AE67BA93897C5534F9DD28C5D33929CB93F3C6BEB11529D637E726B4B8BA3E6718CBA0A98EA4234E7B037832&originRegion=eu-west-1&originCreation=20211011083723*

- *A rapid systematic review of the efficacy of face masks and respirators against coronaviruses and other respiratory transmissible viruses for the community, healthcare workers and sick patients, C.RainaMacIntyre, 21/04/2020,* *https://reader.elsevier.com/reader/sd/pii/S0020748920301139?token=857EDA823EBD6BFB879839D0560572BD86C8CAEE12723621331BCFC07AEB4DFA3BC13CD8CDA84F8C3114CB3045D81C82&originRegion=eu-west-1&originCreation=20211011084012*

- Efficacy of face mask in preventing respiratory virus transmission: A systematic review and meta-analysis, *Mingming Liang, 07/2020,* *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7253999/*