



## EU DECLARATION OF CONFORMITY

**The Manufacturer:** Tiki Safety AB  
Skällstavägen 9  
SE-19740 Bro  
Sweden

### Product Description

Medical Device Class 1 outlet filter is intended for removing particles from the outlet air of a PPE mask.

**Brand name:** Tiki Exhalation Filter

**Model:** 1005-11

The Producer / the Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Produce / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended solely in accordance with the Producers / the Manufacturer's instructions.

### The Conformity is assessed especially with the following provisions:

- Government Regulation no. 93/42/EEC Medical devices establishing technical requirements for medical devices, in effective wording.
- Technical standard EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods.
- Other relevant harmonized legislation.
- Other relevant local, national and community standards.

### For the assessment of conformity, the following documents were also applied to:

- Results of laboratory tests RISE Testing Laboratory BFE
- Results of laboratory tests RISE Testing Laboratory Microbial Cleanliness
- Results of laboratory tests DEKRA Testing Differential Pressure according to EN 12942:1998+A2:2008

### Marking, Labelling

Annex 1, paragraph 13, of the Medical Devices Directive (93/42/EEC) or Annex 1, paragraph 23 of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the product is supplied.

Type of product. EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.

### Measures to Ensure Conformity

The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

Stockholm, 2021-02-09

A handwritten signature in blue ink, appearing to read "Mikael Klockseth".

Mikael Klockseth  
CEO