EC-DECLARATION OF CONFORMITY
EG-KONFORMITÄTSERKLÄRUNG
DÉCLARATION DE CONFORMITÉ CE
CE-CONFORMITEITSVERKLARING

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer:
The manufacturer
Der Hersteller
Le fabricant
De fabrikant

Tiki Safety AB
Skällstavägen 9
SE-19740 Bro
Sweden

declares that the new Personal Protective Equipment (PPE) described hereafter
erklärt hiermit, daß die nachstehend beschriebene neue Persönliche Schutzausrüstung (PSA)
éclare que l'Equipement de Protection Individuelle (EPI) neuf décrit ci-après
verklaart dat het hierna beschreven nieuwe Persoonlijke Beschermingsmiddel (PBM)

Full face mask TIKI Respirator
Vollmaske TIKI Respirator
Masque-complet TIKI Respirator
Volgelaatmasker TIKI Respirator

is in conformity with the provisions of PPE Regulation 2016/425 (EU) and with the harmonized standard **EN 12942:1998+A1:2002+A2:2008 Klasse TM3** and is identical to the PPE which was subject of the EC type examination certificate **Nr. 729233** issued by:

übereinstimmt mit den Bestimmungen der Richtlinie 2016/425 (EU) und übereinstimmt mit der harmonisierten Norm **EN 12942:1998+A1:2002+A2:2008 Klasse TM3** sowie identisch ist mit der PSA, die Gegenstand der EG-Baumusterprüfbescheinigung **Nr. 729233** war, ausgestellt von:

est conforme aux dispositions de la directive 2016/425 (EU) et à la norme harmonisée **EN 12942:1998+A1:2002+A2:2008 Klasse TM3** et est identique à l'EPI ayant fait l'objet de l'attestation CE de type **Nr. 729233** délivrée par:

conform is aan de eisen van Richtlijn 2016/425 (EU); conform is aan de eisen van de Europese geharmoniseerde norm **EN 12942:1998+A1:2002+A2:2008 Klasse TM3**; identiek is aan het PBM, volgens "CE"type-onderzoek **Nr. 729233** uitgegeven door:

BSI Group (2797)
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands

und dem Verfahren unterliegt nach Artikel 19 Modul C2 (CE 729234) der Verordnung (EU) 2016/425 unter der Kontrolle der gemeldeten Stelle:

is subject to the procedure set out in article 19 module C2 (CE 729234) of Legislation (EU) 2016/425 under the supervision of the notified body:

est soumis à la procédure visée à article 19 module C2 (CE 729234) de réglementation (UE) 2016/425 sous le contrôle de l'organisme notifié:

en volgens artikel 19 module C2 (CE 729234) van de verordening (EU) 2016/425 onderworpen is aan het toezicht van de genotificeerde organisatie:

BSI Group (2797)
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands

Stockholm, 2020-10-29

Mikael Klockseth
CEO

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

Mikael Klockseth
CEO