# CERTIFICATE
# OF NON-APPLICABILITY OF CE MARKING

**CERTIFICATE NUMBER:** 22NOCE0909HZ01

**ISSUE DATE:** 9 September 2022

**REPORT REFERENCE:** 22NOCE0909HZ01

**APPLICANT:** TMC

Voert 18 Bergen 1861PE Netherlands

**THIS IS TO CERTIFY THAT ON THE BASIS OF A DOCUMENTATION REVIEW AND REGULATORY RESEARCH FOR :** **Breathetec Anti-snörkbeugel**

Model Number(s)/SKU(s): Smart

ASIN:

EAN:

Alura Group BV confirms the specified product(s) are **NOT** covered by European Union Regulations and Standard(s) that require affixing the CE marking. **Affixing of the CE Marking to these products is unlawful and may lead to corrective measures and prosecution by the market surveillance authorities of the European Union Member States.**

**ADDITIONAL INFORMATION:**

Considering the intended purpose of the Breathetec Anti-snörkbeugel also is not a medical device as defined by the Medical Device Regulation (EU) 2017/745. The Breathetec Anti-snörkbeugel is intended to be used strictly as an anti-snoring device, to prevent the nuisance of snoring. It is specifically not intended to be used to prevent or treat obstructive sleep apnea (OSA). Unlike apnea, snoring is not a medical condition or a disease. Therefore, the Breathetec Anti-snörkbeugel does not fall within the scope of the Medical Device Regulation (EU) 2017/745. No other EU directive or regulation requiring the affixing of the CE marking applies.

The Breathetec Anti-snörkbeugel does fall within the scope of the European Union General Product Safety Directive (2001/95/EC). This EU does require the product to be safe, but the CE marking shall not be affixed on the basis of the General Product Safety Directive (2001/95/EC).

On behalf of Alura Group BV:

Johannes Zuyderwijk

Managing Director

This certificate is based on the results of a review of the product documentation and regulatory research for the abovementioned product. It does not imply a conformity assessment of the product or production. Other non-CE Marking regulations and standards may apply.