FDA IMPORT DECLATION

Exporter:
Viamed Ltd.
[Your Address]
United Kingdom

Date: [Insert Date]

To Whom It May Concern,

We hereby declare that the following product:

Product Name: Maxtec MaxO_2+AE Oxygen Analyzer
Model: R217P72
Manufacturer: Maxtec, LLC, USA

is a medical device that complies with applicable United States Food and Drug Administration (FDA) regulations.

FDA Regulatory Information:

- **FDA Establishment Registration Number (Manufacturer):** 1722070
- **Device Classification:** Class II Medical Device
- **Regulation:** 21 CFR 868.1720 – Oxygen Gas Analyzer
- **FDA Product Code:** CCL

The above device is **FDA listed** by the manufacturer and is legally marketed in the United States. The device forms part of the MaxO_2 oxygen analyser product family, which has been cleared for marketing through the FDA 510(k) premarket notification process.

Viamed Ltd. is acting solely as the exporter/distributor of this product and is not the manufacturer.

This declaration is provided in good faith to support importation into the United States.

Signed:
Name:
Viamed Ltd.

Position: [Your Position]
Email: [Your Email Address]
Telephone: [Your Telephone Number]
