

**FORSCHUNGSINSTITUT FÜR KLINISCHE MEDIZINTECHNIK**

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**Certification**

***Nebulizer Performance Test Result***

**Brand: Vivocare / Type: Doggy**

**OBL Manufacturer: TRIMPEKS ITH. IHR. TUR. ve TIC. A.S., Istanbul, Turkey**

It is hereby certified, that the above given compact piston-type nebulizer, **Vivocare Doggy**, has been tested by Rossmax Int. Ltd under the subsequent review of the FIMT (Asperg, Germany) regarding

- (1) the aerosol particle size distribution
- (2) nebulization output rate (including medication delivery)
- (3) effective residual volume
- (4) Reliability in long-time operation.

Tests have been provided according to the standards and regulations given with EN13544 – 2009 (Respiratory Therapy Equipment-Part 1: Nebulizing Systems and their Components) and the FDA Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators-1993.

The aerosol particle size was tested by two independent methods, the Malvern Spraytec Reflectometry Technique (A), as well as the Marble 298 Cascade Impactor Method (B).

In (B), The **Vivocare Doggy** complies with the medically requested mass median aerodynamic diameter MMAD < 5 [µm] as well as with the enhanced specifications of MMAD < 3 [µm]: MMAD (2.5% NaF) is found as being 2.43 [µm] with a fine particle dose FPD of 76.48 %. In (A), the Dv(50) proved to be < 4 [µm] in open valve condition and < 4.8 [µm] in closed valve condition.

The nebulization rate, including the application of ipratropium bromide, flixotide, terbutaline sulphate and salbutamol resulted in a flow > 0.249 [ml/min] in open valve condition and a flow of > 0.107 [ml/min] in closed valve condition.

The residual volume has been < 0.66 [ml] in both closed and open valve status.

The reliability test disclosed no parameter degradation: A MMAD of ≤ 2.77 [µm] and a nebulization rate ≥ 0.26 [ml/min] was found within all of the 400 [h] operation period.

The evaluation results fully qualify the **Vivocare Doggy** nebulizer for the intended medical use, especially regarding a clinical application on children, due to the given child-friendly design.

Asperg, January 26, 2015

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The Director of the FIMT (Asperg)