FORSCHUNGSINSTITUT FÜR KLINISCHE MEDIZINTECHNIK
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Certification

Nebulizer Performance Test Result

Brand: Vivocare / Type: Breathy

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

It is hereby certified, that the above named piston type nebulizer, ***Vivocare Breathy***, has been tested by Rossmax Int. Ltd, TPE, ROC, 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.

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).

The nebulizer ***Vivocare Breathy*** complied with the medically required median aerodynamic diameter MMAD < 5 [µm] as well as with the tightened specification of MMAD < 3 [µm]: In (B) MMAD is found as being 2.19 [µm] with a fine particle dose FPD of 80.75 %.

The nebulization rate, including the application of ipratropium bromide, flixotide, terbutaline sulphate and salbutamol resulted in a flow > 0.6 [ml/min] in open valve condition and a flow of > 0.2 [ml/min] in closed valve condition.

The residual volume has been < 0.7 [ml] in both, closed as well as open valve status.

The nebulizer ***Vivocare Breathy*** fully qualifies for a medical application consistent with the clinically approved purposes.

Asperg, January 26, 2015.

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The Director of the FIMT (Asperg).