FORSCHUNGSINSTITUT FÜR KLINISCHE MEDIZINTECHNIK
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Certification

Nebulizer Performance Test Result

Brand: Plusmed / Type: pM-N01

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

It is hereby certified, that the above listed heavy duty piston type nebulizer, ***Plusmed pM-N01***, 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.

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 methods, the Malvern Spraytec Reflectometry Technique (A), as well as the Marble 298 Cascade Impactor Method (B).

The ***Plusmed pM-N01*** complies with the medically requested mass median aerodynamic diameter MMAD < 5 [µm] as well as with the Rossmax specification of MMAD < 3 [µm]: In (B) MMAD is found as being 2.07 [µm] with a fine particle dose FPD of 81.4 %, in (A) the Dv(50) is found as being < 3.3 [µm] in open valve condition and Dv(50) < 3.5 [µm] in closed valve condition.

The nebulization rate, including the application of ipratropium bromide, flixotide, terbutaline sulphate and salbutamol resulted in a flow > 0.65 [ml/min] in open valve condition and a flow of > 0.23 [ml/min] in closed valve condition.

The residual volume has been < 0.68 [ml] in both closed and open valve status.

The nebulizer ***Plusmed pM-N01*** fully qualifies for the intended medical application and is especially consistent with a sustained therapeutic use on patients.

Asperg, January 26, 2015

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The Director of the FIMT (Asperg).