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Certification

Nebulizer Performance Test Result

Type: NC-200

Manufacturer: Rossmax Int. Ltd., Taipei, Taiwan

It is hereby certified, that the above listed mesh-type nebulizer, ***Rossmax NC-200***, has been tested by Rossmax Int. Ltd followed by the subsequent independent review of the FIMT (Asperg, Germany) regarding

(1) the aerosol particle size distribution by 2 independent methods

(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 has been assessed by two methods, the Marble 298 Cascade Impactor Method (A), as well as the Malvern Spraytec Reflectometry Technique (B).

The ***Rossmax NC-200*** nebulizer complies with the clinically requested mass median aerodynamic diameter MMAD < 5 [µm] as well as the tighter Rossmax mesh-type specifications of MMAD < 3.5 [µm]: With method (A) applying 2.5 [ml] of 2.5 % NaF, the MMAD is found to be 3.05 [µm] with a fine particle dose FPD of 76.57 %. Applying method (B) with a 2.5 [ml] isotonic saline solution, the mean Dv(50) is found to be < 5.45 [µm].

The nebulization rate, tested with a 2.5% NaF solution, resulted in a gas flow ≥ 0.35 [ml/min].

The residual volume proved to be ≤ 0.08 [ml] by nebulizing 2 [ml] of 0.9% isotonic saline.

The mesh-type nebulizer ***Rossmax NC-200*** fully qualifies regarding the intended medical application in both, children as well as in adults, and is especially suitable for a sustained therapeutic use in respiratory patients.

Asperg, July 15th, 2021.

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