

May 29, 2020

Manufacturer: DemeTECH Corporation
Address: 14175 NW 60 Avenue
Miami Lakes, FL 33014, USA

Quality System: The quality management system of the manufacturer has been certified by the notified body DQS Medizinprodukte GmbH according to EN ISO 13485:2016 as an MDD 93/42/EEC MOD5 compliant system

FDA Classification: Class II (special controls). The special control for this device is FDA's Class II Special Controls Guidance Document: Guidance for Industry and FDA Reviewers on the Content and Format of Premarket Notification [510(k)] Submissions for Surgical Mask. See 878.4040 for the availability of this guidance document.

We, the manufacturer with sole responsibility, hereby declare that the DemeMASK Surgical Masks conform to ASTM 2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks. The products described above and the manufacturing site are subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

Standard	Parameter	Level 3 Specification
ASTM F2101	Bacterial Filtration Efficiency (BFE)	≥ 98%
ASTM F2299	Particle Filtration Efficiency (PFE)	≥ 98%
ASTM F1862	Resistance to Penetration by Synthetic Blood (Fluid Resistance)	Pass at 160 mmHG
	Differential Pressure (Delta-P) Test	< 6 mmH ₂ O/cm ²
16 CFR 1610	Flammability	Class 1



Tracy Chadwick
Quality Director
Date