

Guidance: Prescribing the Lung Flute for Home Care®

INTRODUCTION

The Lung Flute is a Class II Medical Device in the USA [FDA 510(k) K060439 and K091557] and can only be dispensed on order of a physician. The FDA requires that all orders shipped to addresses in the United States include a prescription from a healthcare provider.

The Lung Flute has two FDA 510 (k) “Indications-for-Use”:

- The Lung Flute is indicated for the collection of sputum samples for laboratory analysis and pathologic examination” (FDA 510(k) number K060439)
- The Lung Flute is indicated for Positive Expiratory Pressure (PEP) Therapy” (FDA 510(k) number K091557)

WRITING PRESCRIPTIONS

Prescriptions from the following medical professionals are accepted:

- Primary Care Physician
- Internist
- Sleep Physician
- Nurse Practitioner
- Doctor of Osteopathy
- Physician’s Assistant
- Dentist

“Unlimited” or “Lifetime” or “99 months” prescriptions are good for subsequent orders indefinitely. Without this designation, the patient will need a prescription with each reorder of the Lung Flute.

If a prescription notes an expiration date, it is valid through the listed date.

SUBMITTING PRESCRIPTIONS

Prescriptions may be sent by you or your patient as follows:

- Fax: +1 (716) 608-1362
- E-mail: prescription@medicalacoustics.com
- Mail: Medical Acoustics, PO Box 327, Bowmansville, NY 14026