

1. PRODUCT DESCRIPTION

A lung exerciser is an apparatus made of plastic body and a plastic piston for measuring the volume of air inspired and expired by the lungs. A spirometer measures ventilation, the movement of air into and out of the lungs. Duration of Use: Transient Use. Material of Composition: PC, PP, ABS, LDPE

2. INTENDED PURPOSE

A lung exerciser is an apparatus used to measure the volume of air inspired and expired by the lungs.

3. DEVICE CLASSIFICATION AND RULE

The device is classified as Class Is/Rule 5, medical device (classification as per ANNEX–VIII of (EU) MDR 017/745).

4. PRODUCT CHARACTERISTICS

Lung Exerciser is a hand-held medical device. It is used for the measurement of Inspiration and Expiration capacity of the patient during lung function test and also for the exercise of the lungs / breathing exercise (inspiration).

Lung Exerciser helps to open airway and prevent fluid or mucus from accumulating in Lungs. It also helps to maintain lung strength, or it helps lungs get stronger after an injury or illness.
It also helps to manage a Lung condition such as COPD, Pneumonia, or Asthma.

Features:

- Three flow rate 600 ml/sec, 900ml/sec, and 1200ml/sec are identified by three different colour balls.
- E.V.A connecting tube is very flexible for easy manoeuvring.
- P.P. flash free rounded surface mouth piece is for user comfort.
- Lung exerciser is to be used post covid and cardiac surgery on recommendation of surgeon / paramedic staff.

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- By using lung exerciser can help to open airway and prevent fluid or mucus from accumulating in lungs.
- Component body made of polycarbonate for better strengthen & transparency.
- Supplied Non Sterile.
- To be cleaned by mild detergent and use for lot to water to wiper of the detergent.

5. PRODUCT VARIANTS

Following variants are available for the products:

S. No.	Product	Gauge/Size	GMDN Code	Classification
1.	Lung Exerciser	3 Ball with flow rates 600ml/sec, 900ml/sec and 1200ml/sec	13674	Is

6. PRODUCT SPECIFICATION

Type	Packing Inner/ Outer Unit
Lung Exerciser	1/20

7. PACKAGING DETAILS and SPECIFICATIONS

ITEM	MATERIAL
Primary Packing	Pouch Packaging
Inner Carton	Kraft Pulp Paper
Master Carton	Kraft Pulp Paper

8. COMPLIANCE INFORMATION

Manufacturing Site Information:

Disposafe Health and Life Care Limted,

Plot No. 1 & 2, Phase-II Sec-59, Ballabgarh,

Faridabad, Haryana-121004 (INDIA)

Drug Manufacturing License No.: MFG/MD/2019/000106

QMS Certification: EN ISO 13485:2016

CE Marking: TUV-SUD Product Services GmbH

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