

## Consultative Meeting Notification 41/2017

**Buyer-seller consultation on Endotracheal or Tracheotomy  
Sets – ET Tube with Tapered Shaped Cuff with Subglottic  
Suction dated 06.12.2017**

Presented by :

Date :





## Consultative Meeting Notification 41/2017

### **Buyer-seller consultation on ENDOTRACHEAL Or TRACHEOTOMY SETS –ET TUBE WITH TAPERED SHAPED CUFF WITH SUBGLOTTIC SUCTION dated 06.12.2017**

Consultative Meeting held on 06<sup>th</sup> December 2017 for with sellers and buyers. Following participated in the meeting:

#### **Sellers Participants**

1. M/s HOSPIMAX
2. M/s AMBU
3. M/s Track Manufacturing
4. M/s La-med healthcare (P) Ltd
5. M/s Hansraj Nayyar Medical
6. M/s Syana Health care
7. M/s Medexcel impex pvt. Ltd.

#### **Buyers Participants**

1. AIIMS
2. SAFDARJUNG HOSPITAL
3. RML HOSPITAL
4. LHMC & SSKH
5. SDDMSC
6. LBS HOSPITALS

1. Following **Golden parameters** were decided based on the suggestions and discussions –
  - a) Material of Tube
  - b) Inner Diameter (I.D)
  - c) Cuff Resting Diameter
  - d) Overall length
  - e) Method of sterilization
2. Following changes were decided in the existing TP based on the suggestions and discussions-
  - a) The description of the item should be “ Endotracheal Tube With Tapered Shaped Cuff With Subglottic Suction”
  - b) Parameter “Purpose of ET Tube with tapered shaped cuff with subglottic suction” is to be modified as “To prevent micro aspiration of fluid into the lungs”
  - c) No need of repeating “with tapered shaped cuff with subglottic suction “ in each parameter
  - d) Material of ET Tube ( Non-toxic, Medical Grade)– 100% Silicon, 100% PVC and Silicon coated PVC



- e) Sizes –7.5 and 8.5, are to be added.
- f) I.D of the tube clearly marked on the pilot balloon and tube – Mandatory
- g) Cuff with one way inflation valve and Magill curve
- h) Cuff shape – Barrel, Pear to be added
- i) Kink resistant thermo sensitive tube
- j) Low pressure, high volume Cuff – Mandatory
- k) Latex free-Yes (mandatory)
- l) ET tube shall enable continuous or intermittent secretion through subglottic drainage
- m) Pilot Balloon-Yes and NO both
- n) Intubation depth marking – Mandatory
- o) Method of Sterilization- (1) ETO, (2) Gamma and (3) Others to be added.
- p) Tissue implantation Testing certificate – Mandatory
- q) Non-toxic to be deleted as it is part of the material
- r) Certification – Must Declare ISO/European CE/US-FDA
- s) Manufacturing Drug License- Yes
- t) Authority of Drug License- Must Declare
- u) Drug license No. - Must Declare
- v) Drug license Date- Must Declare
- w) The product should have shelf life of at least 2/3 rd of the total shelf life at the time of supply
- x) All certification to be provided to the buyer on demand

Regards  
Gem-Admin