

## Consultative Meeting Notification 36/2017

**Buyer-seller consultation on Urethral Urinary Catheter**  
**dated 04.12.2017**

Presented by :

Date :



## Consultative Meeting Notification 36/2017

### **Buyer-seller consultation on Urethral urinary catheter dated 04.12.2017**

Consultative Meeting held on 04<sup>th</sup> December 2017 for with sellers and buyers. Following participated in the meeting:

#### **Seller participants:**

No OEM/Seller participated

#### **Buyer participants:**

- 1) Safdarjang Hospital
- 2) RML Hospital

1. Following **Golden parameters** were decided based on the suggestions and discussions –

1. Patient Category
2. Material
3. Type of Balloon
4. Size of Catheter (FG)

2. Following changes were decided in the existing TP based on the suggestions and discussions–

1. Material- Medical grade, non-toxic - 100 % Silicon, 100 % Latex with Silicon Coating, 100 % Silicon Bonded Latex
2. Type of Balloon Catheter- Catheter without balloon to be added
3. Size 28 and 30 to be added
4. Smooth eyes to provide easy insertion- mandatory
5. Large eye for smooth drainage- - Mandatory
6. Balloon Capacity and Tube outer diameter to be declared
7. Standard- Conforming to F623-99 / BSEN 1616 :1997
8. Product Certification- CE/ others/NA
9. Product Certification to be provided to the buyer on demand
10. Certification for the manufacturing premises—Must declare (ISO 13485/CE/US-FDA/others/NA)
11. Manufacturing Drug Licence- Yes
12. Authority of Drug Licence- Must Declare
13. Drug licence No. - Must Declare
14. Drug licence Date- Must Declare
15. The product should have shelf life of at least 2/3 rd of the total shelf life at the time of supply
16. All certification to be provided to the buyer on demand

Regards

GeM-Admin

