

*TECHNICAL SPECIFICATIONS  
OF MEDICAL DEVICE:*

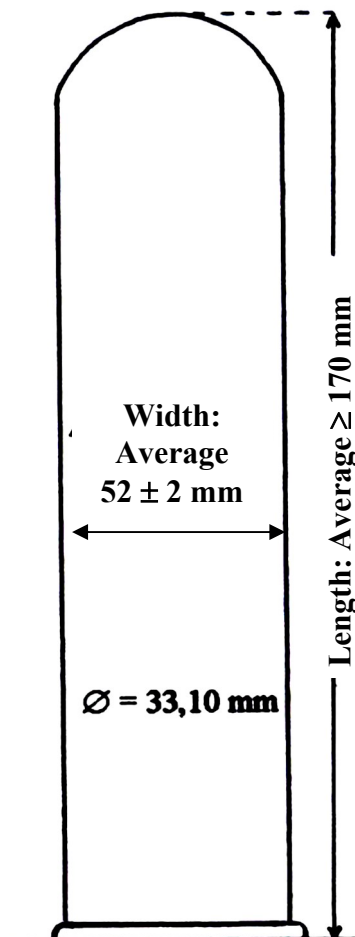
**LATEX PROBE COVER FOR VAGINAL & ANAL ULTRASOUND SCANNING**

**1. DESCRIPTION OF PRODUCT:**

Classification: **IIa** (according to Medical Device Directive EEC/93/42).

Description: 1.- **Smooth, parallel-sided, no receptacle-ended and transparent colour.**

**2.- DESIGN OF PRODUCT:**



**3.- DESIGN SPECIFICATIONS IN ACCORDANCE WITH TECHNICAL SPECIFICATIONS OF CEX INTERNACIONAL S.A.**

<i>Test</i>	<i>Samples Number</i>	<i>Acceptance Criteria</i>
Dimensions	10	Length: Average $\geq 170$ mm Width: Average: $52 \pm 2$ mm
Bursting Volume & Pressure	Special Inspection Level: S-4 as in ISO 2859-1	AQL of 1,5 Minimum Bursting Volume: 15 dm <sup>3</sup> Minimum Bursting Pressure: 1,0 kPa
Mechanical Properties (& Oven treatment)		
Force at Break of test pieces	13	Median $\geq 39$ N
Elongation at Break of test pieces	13	Median $\geq 700$ %
Freedom from holes test	General Inspection Level: I as in ISO 2859-1	AQL of 0,4
Packaging and Labelling	10	All must comply. Medical Device Directive 93/42/EEC (Annex I).

*NOTE: ISO 2859-1: Sampling procedures for inspection by attributes*

*Part 1: Sampling plans indexed by a acceptable quality level (AQL) for lot-by-lot inspection.*

## **4.- INSTRUCTIONS**

### **FOR USE**

- Avoid touching the latex probe cover with sharp nails, rings, etc. Handle carefully when you remove it from its package.
- Place the coupling gel for ultrasound scanner inside the latex probe cover.
- Unroll the latex probe cover carefully over the ultrasound scanner or probe.
- The latex probe cover can be used just once. Never wash it.
- To lubricate it, use only water-based coupling gels. The oily lubricants can damage the latex probe cover.
- This product contains natural rubber latex which may cause allergic reactions.
- Check the expiry date printed in the package.

### **FOR STORAGE**

- Keep the latex probe covers in a cool dry place away from sunlight and heat.
- Do not take them out of its package until the moment of use.

### **FOR DISPOSAL**

- After use it, throw out the latex probe cover in a container for refuses of medical devices.