

RNDM CODE 1403109/R  
CND CODE: W050302010102

<u>Code</u>	<u>Description</u>	
<b>18436</b>	<b>POLYETHYLENE PASTEUR PIPETTE GRADUATED UP TO 1 ML</b>	
<b><u>Dimensions and specifications:</u></b>		
<b>Length:</b>	<b>150 mm</b>	
<b>Capillary external diameter:</b>	<b>5 mm</b>	
<b>Tip external diameter:</b>	<b>2,5 mm</b>	
<b>Capillary graduation:</b>	<b>0,25-0,5-0,75-1 ml</b>	
<b>Total volume:</b>	<b>3,5 ml</b>	
<b><u>Packaging:</u></b>		
<b><i>Single device</i></b>	<b><i>Intermediate packing</i></b>	<b><i>External packing</i></b>
	<b>10 boxes of 500 pieces – label affixed with: CE, REF, quantity, description, batch, expiry, manufacturer</b>	<b>box of 5000 pieces – label affixed with: CE, REF, quantity, description, batch, expiry, manufacturer</b>
<b><u>Destination of use:</u></b>		
<b>POURING AND MANUAL DOSAGE OF BIOLOGICAL LIQUIDS</b>		
This product must be used by skilled operators of biomedical analysis laboratories only.		
<b><u>Material:</u></b>		
<b>POLYETHYLENE</b>		
<b>The material is non-toxic, transparent, particularly resistant to impacts and centrifugation</b>		
<b><u>Shelf life:</u></b>		
<b>Device shelf life: 5 (five) years from the production date</b>		



 Roll srl Via Leonardo da Vinci n.24/A 35028 Piove di Sacco (PD)	 <b>Technical sheet</b>	18436	PAGE 2 OF 2
		REV 6	DATE 02/05/2022

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**Storage and preservation:**

**Storage and preservation of the device for long periods have to be at a temperature between +5 and +25°C, in a dry place**

**Material certifications:**

**All raw materials and materials used are non-toxic, for certified food and medical use, according to the European legislation and FDA (USA) in force**

**Sterilization:**

**No treatment**

**Quality system applied for the production and reference regulations:**

**UNI EN ISO 9001:2015 ICIM current certificate no 4264/5 issued by ICIM S.p.a.**

**UNI EN ISO 13485:2016 ICIM current certificate no 4265/5 issued by ICIM S.p.a.**

**CE: quality guarantee system through issue of CE Declaration of Conformity after preparation of technical-productive dossiers as per Directive EEC 98/79/CE available to the competent authority**

**UNI CEI EN ISO 15223-1 Symbols to be used with medical device labels, labelling and information to be supplied**

**UNI EN 1041 Information supplied by the manufacturer of medical devices**

**UNI EN 14971 Application of risk management to medical devices**

**Disposal modality:**

**Before use, they have to be considered non-hazardous waste to be disposed of according to Legislative Decree 156/06 as amended.**

**After use, they have to be considered sanitary waste potentially infected: CER 18 01 03\* waste that have to be collected and disposed of, by applying particular precautions to avoid infections.**

Prepared by .....	Controlled by .....	Approved by .....
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