



## LP ITALIANA SPA

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### TECHNICAL DATA SHEET

## LP SEROLOGICAL PIPETTES

Quality and functionality are the main objectives to which the production of LP Serological Pipettes is aimed.

Production range.

**Standard:** seven nominal volumes:

1 ml - 1,1 ml - 2 ml - 2,2 ml - 5 ml - 10 ml - 25 ml

**Variations:** 1 ml, 2 ml, 5 ml, 10 ml open-end pipettes are dedicated for applications involving dense liquids. They differ from the standard versions as they do not have a tapered end.


**Packaging and microbiological state:** see Table A

**Structure:** all LP serological pipettes are produced in a **single piece**, without any junction. This characteristic is one of the most appreciated by users, because it eliminates leakages during aspiration, and above all during delivery. This ensures precision of the delivered volume and at the same time the total emptying of the pipette, and therefore avoiding the retention of liquids within the pipette, which alter the last volume delivered.

**Cross contamination:** traditionally, as with almost all the competitive products, the means of slowing down the flow of excess liquid is made by a cotton wad inserted by pressure near the rear of the pipette. The amount of cotton and its positioning varies, and can be easily moved from its original site. On the contrary, LP serological pipettes have **safety filters** with controlled constant porosity and density. They are located in a constantly fixed position near the rear of the pipette. Besides the quality of the job performed by the filter, the following are also eliminated: loss of contaminants, particles, filaments and other, from the cotton wad. The controlled porosity and density practically eliminate the contamination risk for the operator (in case of aspiration is made by mouth) and any cross contaminations caused by liquids in contact with the automatic pipettor.

The filters with controlled porosity also contribute to improve the quality of delivery by the operator.

**Material:** LP serological pipettes are produced with a special biologically inert transparent material. This makes it possible to obtain an almost flat meniscus within the pipette.

Firma: 	Distribuito a: DG - DVE - VEI - VEE - UA
Documento: RSSG 138 Rev. E	Pag. 1 di 4 Data Emissione: 03.04.2013

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## Accuracy, Precision, Uncertainty

The total error of a measurement, without any gross errors, can be expressed as the sum between a systematic component (Inaccuracy) and a random component (Imprecision).

Accuracy degree of conformity of a measured value to its actual (true) value;

Precision degree to which several measurements show the same or similar results;

Uncertainty of a measurement is stated by giving a range of values which are likely to enclose the true value. It depends on the graduation, on the visual acuteness, on fluctuations of the pointer, and from the mechanical or the electronic instability (non applicable to the pipettes).

LP serological pipettes have:

$$\text{INACCURACY} < \pm 1\%$$

$$\text{IMPRECISION} < 2\%$$

The quantification of imprecision is supplied only to satisfy the market's habit to see it indicated. However it is to be noted that it should not be applicable to serological pipettes for the following reasons:

1 – the volumetric graduation of the pipettes is responsible for inaccuracy (geometric tolerance of the tube, geometric and spatial error of the graduation)

2 – the pipette itself cannot be responsible for imprecision due to the following:

2.1 – if used with a pipettor, the agreement between the aspirated or delivered volumes is a function of the precision of the pipettor and/or the operator's handling ability

2.2 – if used manually (visually), the agreement between the aspirated or delivered volumes is a function of the uncertainty, as described above, and therefore not dependent on the pipette itself.

**Graduation:** is made using bright and indelible colors for better contrast and ease of reading, and conforms to the models of norm ISO 835 part 1 and 2. LP serological pipette also have a negative graduation, proportioned to current use, and also of reverse graduation (see Table A).

**Color coding:** a wide and brightly colored band is placed at the filter end of the pipette to assure easy identification. Conforms to the internationally recognized norm ISO 1769. See table A for color listing.

### In addition, only for applicable cases:


**Sterilization:** LP serological pipettes are sterilized made by ionizing radiation conforming to a validated method, in accordance to ISO 11137-1:2006; ISO 11137-2:2012 and Tech. Corr. 2009, ensuring a SAL (Sterility Assurance Level) of  $10^{-6}$ . This is guaranteed until the packaging is opened, with a shelf life of 5 years. The sterilization process is kept under control by LP through random periodical tests. A lot certification can be made available if specifically requested at the time of order.

**Pyrogen free:** due to the particular production and packaging procedure, LP serological pipettes are normally endotoxin free, and therefore are pyrogen free. LP keeps the production process under control through random periodical laboratory tests.

A lot certification can be made available if specifically requested at the time of order.

**DNase - RNase:** due to the automatized production and packaging methods, LP serological pipettes are normally free of these enzymes. LP keeps the production process under control through random periodical laboratory tests.

A lot certification can be made available if specifically requested at the time of order.

Firma: 	Distribuito a: DG - DVE - VEI - VEE - UA
Documento: RSSG 138 Rev. E	Pag. 2 di 4 Data Emissione: 03.04.2013

# LP ITALIANA SPA

**Packaging:** produced in various packaging versions, are contained in thick polyethylene bags and individually wrapped in blisters with a PA/PE film and medical grade paper which does not release particles during opening.


**Intended use and CE marking:** according to the specifications, the pipettes can be assigned for general laboratory use. However, LP ITALIANA indicates as the pipette's intended use that of transporting fluid samples coming from the human body, in specific the serum part of human blood, to be tested for the determination of the physiological or pathological state of a patient. For this reason, the pipettes are covered by the Italian Legislative Decree 332 of September 8, 2000, in harmonization of the European Directive 98/79/CE for In Vitro Medical Diagnostic Devices (IVD). Based on this, our pipettes are CE marked. The same applies to those pipettes which are in the specific microbiological state indicated by

STERILE R

**Disposal:** LP serological pipettes can be disposed in several ways:

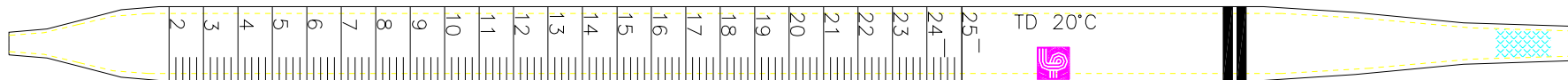
1. If not contaminated they are completely recyclable (taking into consideration the presence of the paints).
2. Can be used for energy recovery. In such case no additional gas is needed.
3. Can be sent to a landfill (in accordance with local regulations) where they do not create percolation.
4. Can be disposed by incineration respecting anti-pollution norms, because during combustion they release only water and carbon dioxide (combustion with sufficient air insufflation and adequate temperature).




Firma: 	Distribuito a: DG - DVE - VEI - VEE - UA
Documento: RSSG 138 Rev. E	Pag. 3 di 4 Data Emissione: 03.04.2013

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Table A: Nominal Volume	Volume Total graduated volume	Graduation				Color Code	Mouth Diameter	Total length	Packaging		
		from	to	Minimum division	negative				Single / code	Multiple / code	
Tapered	ml	ml	ml	ml	ml		mm	mm	Sterile	Sterile	Non Sterile
1	1,2	0,9	-0,2	1/100	0,2	Yellow	5,1 <sup>±0,05</sup>	272 <sup>±3</sup>	Yes / 160110	Yes / 160111	Yes / 160119
1,1	1,1	0,5	1,1	1/10	-	-	5,1 <sup>±0,05</sup>	272 <sup>±3</sup>	No	Yes / 161111	No
2	2,2	1,84	-0,2	1/100	0,2	Green	6,2 <sup>±0,10</sup>	272 <sup>±3</sup>	Yes / 160210	Yes / 160211	Yes / 160219
2,2	2,2	0,5	2,2	1/10	-	-	6,2 <sup>±0,10</sup>	272 <sup>±3</sup>	No	Yes / 161211	No
5	6,5	4,3	-1,5	1/10	1,5	Blue	6,25 <sup>±0,15</sup>	322 <sup>±3</sup>	Yes / 160510	Yes / 160511	Yes / 160519
10	11,5	9,2	1,5	1/10	1,5	Orange	7,15 <sup>±0,15</sup>	322 <sup>±3</sup>	Yes / 161010	Yes / 161011	Yes / 161019
25	30	23	-5	2/10	-5	Red	7,45 <sup>±0,35</sup>	342 <sup>±3</sup>	Yes / 162510	No	No
Wide tip											
1	1,2	0,9	-0,2	1/100	0,2	Yellow	5,1 <sup>±0,05</sup>	264 <sup>±3</sup>	no	Yes / 160118	no
2	2,2	1,84	-0,2	1/100	0,2	Green	6,2 <sup>±0,10</sup>	264 <sup>±3</sup>	no	Yes / 160218	no
5	6,5	4,3	-1,5	1/10	1,5	Blue	8,6 <sup>±0,10</sup>	268 <sup>±3</sup>	no	Yes / 160518	no
10	11,5	9,2	-1,5	1/10	1,5	Orange	10,6 <sup>±0,10</sup>	290 <sup>±3</sup>	no	Yes / 161018	no



Firma: 	Distribuito a: DG - DVE - VEI - VEE - UA
Documento: RSSG 138 Rev. E	Pag. 4 di 4 Data Emissione: 03.04.2013