



EC DECLARATION OF CONFORMITY

In accordance with the 98/79/CE – ANNEX III, points applicable to:

Tips and Pipettes for transferring samples of biological fluids coming from the human body

References:

- Groups no. 10, 20, 23, 24 as per Declaration according to D.Lgs. 332/2000 submitted to the Italian Ministry of Health on 08/05/2001
- DIR 98/79 /CE acknowledged by Italy with D.Lgs. 332 of 08/09/2000
- Device Master File n. 02-07- “Serological pipettes, Pasteur pipettes, ESR pipettes, Tips for pipettors”
- Certified Quality Management System to UNI EN ISO 13485:2016

LP ITALIANA SPA

declares

that concerned products from its own catalogue, referred to the product codes in the enclosed list Nr 02 - 07, fulfil the obligations imposed by the Directive, which apply to them, and

meet

the essential requirements provisions set out in Annex I (which apply to them) and

are not contained

in the List A nor List B of **Annex II** of the Directive.

LP ITALIANA SPA keeps at the disposal of the Competent Authorities this Declaration of Conformity, together with the relative Device Master File (cod. FT 02-07) comprising the following documents.

Technical:	<i>General product description including variants</i>	<i>Design information</i>
	<i>Documentation of the Quality System</i>	<i>Risk analysis</i>
	<i>Technical drawings</i>	<i>Direction for use description</i>
	<i>Characteristics of the basic materials</i>	<i>Microbiological state</i>
	<i>Performances and limits</i>	<i>Tests reports</i>
	<i>Method of manufacture</i>	<i>Labelling</i>

and assuring that the relative method of manufacture follows the principles of quality assurance appropriate for these tips and pipettes:

- Methods of manufacture according to adequate QA principles*
- Organizational structure and responsibility*
- Applicable Operating Procedures of LP ITALIANA SPA's Quality Management System*
- Applicable Operating Instructions of LP ITALIANA SPA's Quality Management System*
- Statistical control of production quality*
- Quality Management System performance control means*

LP ITALIANA SPA has instituted and keeps up to date its PO 04.03 systematic procedure, covering the the following aspects:

- *Reviewing the experience gained from tips and pipettes in the post-production phase*
- *Implementation of any appropriate means to apply any necessary corrective actions taking account of the nature and risk in relation to the use of the tips and pipettes*
- *Immediate notification to the Competent Authorities of incidents involving the use of the tips and of the pipettes, on learning of them.*

With the above, LP ITALIANA SPA notifies the Italian Ministry of Health to affix on the the tips and the pipettes, subject of this Declaration, the CE marking of conformity in accordance with the article 16 (17) and Annex X of the mentioned Directives.

LP ITALIANA SPA
Legal Representative
(*Francesco Leopardi*)

Signed in Milan the, 25 May 2022





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List Number:	DMF 02-07 Rev. 10	Date	2018.04.16
EC Declaration of Conformity:	"Tips and Pipettes for transferring samples of biological fluids coming from the human body"		
Product classification:	IVD - "Other Device"		
EC Directive	98/79/CE		
Device Master File Nr	FT 02-07		

Product Code List

Code	Description 	Descrizione 
	Pasteur pipettes	Pipette Pasteur
132038	Polyethylene mini pipette 63 mm, capillary Ø 2,5 mm, volume 1,5 ml, 30 drops/ml, in bags of 20, sterile R	Mini pipetta in polietilene 63 mm, capillare Ø 2,5 mm, volume 1,5 ml, 30 gocce/ml, in sacchetti da 20, sterile R
132138	Polyethylene mini pipette 63 mm, capillary Ø 2,5 mm, volume 1,5 ml, 30 drops/ml, single wrapped, sterile R	Mini pipetta in polietilene 63 mm, capillare Ø 2,5 mm, volume 1,5 ml, 30 gocce/ml, confezione singola, sterile R
133030	Polyethylene mini pipette 87 mm, capillary Ø 4 mm volume 2 ml, 30 drops/ml	Mini pipetta in polietilene 87 mm, capillare Ø 4 mm, volume 2 ml, 30 gocce/ml
133038	Polyethylene mini pipette 87 mm, capillary Ø 4 mm, volume 2 ml, 30 drops/ml, in bags of 20, sterile R	Mini pipetta in polietilene 87 mm, capillare Ø 4 mm, volume 2 ml, 30 gocce/ml, in sacchetti da 20, sterile R
133138	Polyethylene mini pipette 87 mm, capillary Ø 4 mm, volume 2 ml, 30 drops/ml, single wrapped, sterile R	Mini pipetta in polietilene 87 mm, capillare Ø 4 mm, volume 2 ml, 30 gocce/ml, confezione singola, sterile R
134038	Polyethylene pipette 83 mm, capillary Ø 2,5 mm, volume 4 ml, 30 drops/ml, in bags of 20, sterile R	Pipetta in polietilene 83 mm, capillare Ø 2,5 mm, volume 4 ml, 30 gocce/ml, in sacchetti da 20; sterile R
134138	Polyethylene pipette 83 mm, capillary Ø 2,5 mm, volume 4 ml, 30 drops/ml, single wrapped, sterile R	Pipetta in polietilene 83 mm, capillare Ø 2,5 mm, volume 4 ml, 30 gocce/ml, confezione singola, sterile R
135038	Polyethylene macro pipette 150 mm, capillary Ø 7,8 mm, volume 7 ml, 26 drops/ml, in bags of 20, sterile R	Pipetta macro in polietilene 150 mm, capillare Ø 7,8 mm, volume 7 ml, 26 gocce/ml, in sacchetti da 20, sterile R
135138	Polyethylene macro pipette 150 mm, capillary Ø 7,8 mm volume 7 ml, 26 drops/ml, single wrapped, sterile R	Pipetta macro in polietilene 150 mm, capillare Ø 7,8 mm, volume 7 ml, 26 gocce/ml, confezione singola, sterile R
136038	Polyethylene micro pipette 150 mm, capillary Ø 2,5 mm, volume 4 ml, 30 drops/ml, in bags of 20, sterile R	Pipette micro in polietilene 150 mm, capillare 2,5 mm, volume 4 ml, 30 gocce/ml, in sacchetti da 20, sterile R
136138	Polyethylene micro pipette 150 mm, capillary Ø 2,5 mm, volume 4 ml, 30 drops/ml, single wrapped, sterile R	Pipette micro in polietilene 150 mm, capillare 2,5 mm, volume 4 ml, 30 gocce/ml, confezione singola, sterile R
137038	Polyethylene Semi-micro pipette 150 mm, capillary 5 mm, volume 5 ml, 30 drops/ml, in bags of 20, sterile R	Pipette semi-micro in polietilene 150 mm, capillare Ø 5 mm volume 5 ml, 30 gocce/ml, in sacchetti da 20, sterile R
137138	Polyethylene Semi-micro pipette 150 mm, capillary 5 mm, volume 5 ml, 30 drops/ml single wrapped, sterile R	Pipette semi-micro in polietilene 150 mm, capillare Ø 5 mm volume 5 ml, 30 gocce/ml, confezione singola, sterile R
139038	Polyethylene Pipette 230 mm, capillary Ø 4,5 mm, volume 6 ml, 21 drops/ml, in bags of 20, sterile R	Pipette in polietilene 230 mm, capillare Ø 4,5 mm, volume 6 ml, 21 gocce/ml, in sacchetti da 20, sterile R
139138	Polyethylene Pipette 230 mm, capillary Ø 4,5 mm, volume 6 ml, 21 drops/ml, single wrapped, sterile R	Pipette in polietilene 230 mm, capillare Ø 4,5 mm, volume 6 ml, 21 gocce/ml, confezione singola, sterile R
	Dispenser Tips	Puntali dispensatori
154148	Dispenser tips volume 0,5 ml, single wrapped, sterile R	Puntali dispensatori 0,5 ml, confezione singola, sterile R
154248	Dispenser tips volume 1,25 ml, single wrapped, sterile R	Puntali dispensatori 1,25 ml, confezione singola, sterile R
154448	Dispenser tips volume 5 ml, single wrapped, sterile R	Puntali dispensatori 5 ml, confezione singola, sterile R
154548	Dispenser tips volume 12,5 ml, single wrapped, sterile R	Puntali dispensatori 12,5 ml, confezione singola, sterile R
	Tips for Pipetting Devices	Puntali per pipettatori
151048	Tips MLA type 10-200 µl, in bags of 5, sterile R	Puntali tipo MLA 10-200 µl; 5 pz in blister, sterile R
151148	Tips Eppendorf type 5-10 µl, in bags of 5, sterile R	Puntali tipo Eppendorf 0,5-10 µl, 5 pezzi in blister, sterile R
151248	Tips Oxford type 10-200 µl, in bags of 5; sterile R	Puntali tipo Oxford 10-200 µl, 5 pz in blister, sterile R
151348	Tips Eppendorf type 5-100 µl, in bags of 5, sterile R	Puntali tipo Eppendorf 5-100 µl, 5 pz in blister, sterile R
151448	Tips Oxford type 250-1000 µl, in bags of 5, sterile R	Puntali tipo Oxford 250-1.000 µl, 5 pz in blister, sterili R
151648	Tips Eppendorf type 100-1000 µl, in bags of 5, sterile R	Puntali tipo Eppendorf 100-1000 µl, 5 pz in blister, sterili R
151748	Tips MLA type 250-1000 µl, in bags of 5, sterile R	Puntali tipo MLA 250-1.000 µl, 5 pz in blister, sterili R
151948	Tips Sherwood type 10-500 µl in bags of 5, sterile R	Puntali tipo Sherwood 10-500 µl, 5 pz in blister, sterile R
152348	Tips Gilson type 5-200 µl, in bags of 5, sterile R	Puntali tipo Gilson 5-200 µl, 5 pz in blister, sterile R
152648	Tips Gilson type 200-1000 µl, in bags of 5, sterile R	Puntali tipo Gilson 200-1000 µl, 5 pz in blister, sterili R





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Product Code List

Code	Description 	Descrizione 
	Serological Pipette	Pipette per Sierologia
160110	Serological pipette 1 ml narrow tip, single wrapped, sterile R	Pipette sierologia 1 ml a punta stretta, confezione singola, sterile R
160111	Serological pipette 1 ml narrow tip, in bags of 25, sterile R	Pipette sierologia 1 ml a punta stretta, sacchetti da 25 pz, sterile R
160118	Serological pipette 1 ml open end, in bags of 10, sterile R	Pipette sierologia 1 ml a foro largo, sacchetti da 10 pz, sterile R
160210	Serological pipette 2 ml narrow tip, single wrapped, sterile R	Pipette sierologia 2 ml a punta stretta, confezione singola, sterile R
160211	Serological pipette 2 ml narrow tip, in bags of 25, sterile R	Pipette sierologia 2 ml a punta stretta, sacchetti da 25 pz, sterile R
160218	Serological pipette 2 ml open end, in bags of 10, sterile R	Pipette sierologia 2 ml a foro largo, sacchetti da 10 pz, sterile R
160510	Serological pipette 5 ml narrow tip, single wrapped, sterile R	Pipette sierologia 5 ml a punta stretta, confezione singola, sterile R
160511	Serological pipette 5 ml narrow tip, in bags of 25, sterile R	Pipette sierologia 5 ml a punta stretta, sacchetti da 25 pz, sterile R
160518	Serological pipette 5 ml open end, in bags of 10, sterile R	Pipette sierologia 5 ml a foro largo, sacchetti da 10 pz, sterile R
161010	Serological pipette 10 ml narrow tip, single wrapped, sterile R	Pipette sierologia 10 ml a punta stretta, confezione singola, sterile R
161011	Serological pipette 10 ml narrow tip, in bags of 25, sterile R	Pipette sierologia 10 ml a punta stretta, sacchetti da 25 pz, sterile R
161018	Serological pipette 10 ml open end, in bags of 10, sterile R	Pipette sierologia 10 ml a foro largo, sacchetti da 10 pz, sterile R
161111	Serological pipette 1,1 ml narrow tip, in bags of 25, sterile R	Pipette sierologia 1,1 ml a punta stretta, sacchetti da 25 pz, sterili R
161211	Serological pipette 2,2 ml narrow tip, in bags of 25, sterile R	Pipette sierologia 2,2 ml a punta stretta, sacchetti da 25 pz, sterile R
162510	Serological pipette 25 ml narrow tip, single wrapped, sterile R	Pipette sierologia 25 ml a punta stretta, confezione singola, sterile R