



# LP ITALIANA SPA

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## EC DECLARATION OF CONFORMITY

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

### Containers for samples of human body fluids

#### References:

- 2<sup>nd</sup> group as per Declaration according to art. 20 of D.Lgs. 332, 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 Nr. 02-06- "Containers, volume 20 through 180 ml"
- Certified Quality Management System to UNI EN ISO 13485:2016

LP ITALIANA SPA

109047

#### declares

that concerned products from its own catalogue, with microbiological state non sterile, or 

STERILE	A
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or 

STERILE	R
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 referred to the product codes in the enclosed list 02-06, fulfil the obligation 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 02-06) comprising the following documents:

Technical: *General product description including variants*

*Design information*

*Documentation of the Quality System*

*Risk analysis*

*Technical drawings*

*Direction for use description*

*Characteristics of the basic materials*

*Microbiological state*

*Performances and limits*

*Tests reports*

*Method of manufacture*

*Labelling*

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

*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 following aspects:

- *Reviewing the experience gained from containers 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 containers*
- *Immediate notification to the Competent Authorities of incidents involving the use of the containers, on learning of them*

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

LP ITALIANA SPA

Legal Representative

(*Francesco Leopardi*)

Signed in Milan the, 19 January 2021



List Number:	DMF 02-06 Rev. 9	Date	2018.04.16	Sheet	1/2
EC Declaration of Conformity:	<b>"Containers for fluid samples derived from the human body"</b>				
Product classification:	IVD - "Other Device"				
EC Directive	98/79/CE				
Device Master File Nr	FT 02-06				

## Product Code List

Code	Description 	Descrizione 
101010	20 ml scintillation vial, with screw cap; in polyethylene; Ø 27 x 60 mm	Contentitore per scintillazione da 20 ml, con tappo a vite; in polietilene; Ø 27 x 60 mm
101040	Safety urine container for antidoping tests, in single sealed bag	Contentitore di sicurezza per test antidoping urine, in confezione singola
102047	150 ml urine container, in polypropylene; Ø 63 x 65 mm; with detached white screw cap;	Contentitore urine 150 ml, in polipropilene, Ø 63 x 65 mm, tappo bianco a vite, separato;
102048	150 ml urine container, in polypropylene; Ø 63 x 65 mm; with red mounted screw cap; sterile A	Contentitore urine 150 ml, in polipropilene, Ø 63 x 65 mm; tappo rosso a vite; sterile A
102147	150 ml urine container, in polypropylene; Ø 63 x 65 mm; with white mounted screw cap; labelled	Contentitore urine 150 ml, in polipropilene, Ø 63 x 65 mm, tappo bianco a vite; etichettato
102148	150 ml urine container, in polypropylene; Ø 63 x 65 mm; with red screw cap; labelled; sterile A	Contentitore urine 150 ml, in polipropilene, Ø 63 x 65 mm, tappo rosso a vite; etichettato; sterile A
102348	150 ml urine container, in polypropylene; Ø 63 x 65 mm with red screw cap; labelled; individually wrapped; sterile A	Contentitore urine 150 ml, in polipropilene, Ø 63 x 65 mm, tappo rosso a vite; etichettato; confezione singola; sterile A
102548	150 ml urine container, in polypropylene; Ø 63 x 65 mm; with red screw cap; individually wrapped; sterile A	Contentitore urine 150 ml, in polipropilene, Ø 63 x 65 mm, tappo rosso a vite; confezione singola; sterile A
102647	150 ml urine container, in polypropylene; Ø 63 x 65 mm; with white screw cap	Contentitore urine 150 ml, in polipropilene, Ø 63 x 65 mm, tappo bianco a vite;
102748	150 ml urine container, in polypropylene; Ø 63 x 65 mm; with red screw cap; sterile R	Contentitore urine 150 ml, in polipropilene, Ø 63 x 65 mm; tappo rosso a vite; sterile R
102848	150 ml urine container, in polypropylene; Ø 63 x 65 mm; with red screw cap; labelled; individually wrapped; sterile R	Contentitore urine 150 ml, in polipropilene, Ø 63 x 65 mm; tappo rosso a vite; etichettato; confezione singola; sterile R
102948	150 ml urine container, in polypropylene; Ø 63 x 65 mm; with red screw cap; individually wrapped; sterile R	Contentitore urine 150 ml, in polipropilene, Ø 63 x 65 mm; tappo rosso a vite; confezione singola; sterile R
103017	30 ml universal container for human fluids (sputum etc), in polystyrene; Ø 34 x 41 mm, detached white pressure cap	Contentitore universale 30 ml, per fluidi umani (espettorato etc), in polistirolo; Ø 34 x 41 mm, tappo bianco a pressione separato
103018	30 ml universal container for human fluids (sputum etc), in polystyrene; Ø 34 x 41 mm; with yellow pressure cap; sterile R	Contentitore universale 30 ml per fluidi umani (espettorato etc), in polistirolo; Ø 34 x 41 mm; tappo giallo a pressione; sterile R
104017	45 ml universal container for human fluids (sputum etc), in polystyrene; Ø 34 x 60 mm; with detached white pressure cap	Contentitore universale 45 ml, per fluidi umani (espettorato etc), in polistirolo; Ø 34 x 60 mm, tappo bianco a pressione separato;
104018	45 ml universal container for human fluids (sputum etc), in polystyrene; Ø 34 x 60 mm; with yellow pressure cap; sterile R	Contentitore universale per fluidi umani (espettorato etc), in polistirolo; Ø 34 x 60 mm, tappo giallo a pressione montato; sterile R
105047	180 ml urine container, in polypropylene; Ø 63 x 80 mm with detached white screw cap	Contentitore urine 180 ml, in polipropilene, Ø 63 x 80 mm, tappo bianco a vite separato;
105048	180 ml urine container, in polypropylene; Ø 63 x 80 mm; with red screw cap; sterile A	Contentitore per urine 180 ml, in polipropilene, Ø 63 x 80 mm; tappo rosso a vite; sterile A
105147	180 ml urine container, in polypropylene; Ø 63 x 80 mm; with mounted white screw cap; labelled	Contentitore urine 180 ml, in polipropilene, Ø 63 x 80 mm; tappo bianco a vite montato; etichettato
105148	180 ml urine container, in polypropylene; Ø 63 x 80 mm; with red screw cap; labelled; sterile A	Contentitore per urine 180 ml, in polipropilene, Ø 63 x 80 mm; tappo rosso a vite; etichettato; sterile A
105248	180 ml urine container, in polypropylene; Ø 63 x 80 mm, with red screw cap; labelled; individually packed in box; sterile A	Contentitore urine 180 ml, in polipropilene, Ø 63 x 80 mm; tappo rosso a vite; etichettato; confezionato singolarmente in scatola; sterile A
105348	180 ml urine container, in polypropylene; Ø 63 x 80 mm with red screw cap; labelled; individually wrapped; sterile A	Contentitore urine 180 ml, in polipropilene, Ø 63 x 80 mm; tappo rosso a vite; etichettato; confezione singola; sterile A
105548	180 ml urine container, in polypropylene; Ø 63 x 80 mm; with red screw cap; individually wrapped; sterile A	Contentitore urine 180 ml, in polipropilene, Ø 63 x 80 mm; tappo rosso a vite; confezione singola; sterile A
105647	180 ml urine container, in polypropylene; Ø 63 x 80 mm, with white screw cap; sterile A	Contentitore urine 180 ml, in polipropilene, Ø 63 x 80 mm; tappo bianco a vite; Ø 63 x 80 mm; sterile A



Code	Description 	Descrizione 
105748	180 ml urine container, in polypropylene; Ø 63 x 80 mm; with red screw cap; sterile R	Contentitore urine 180 ml, in polipropilene, Ø 63 x 80 mm; tappo rosso a vite; sterile R
105948	180 ml urine container, in polypropylene; Ø 63 x 80 mm; with red screw cap; individually wrapped; sterile R	Contentitore urine 180 ml, in polipropilene, Ø 63 x 80 mm; tappo rosso a vite; confezione singola; sterile R
107027	25 ml polystyrene container, coulter counter type; Ø 33 x 60 mm; with natural white pressure cap	Contentitore da 25 ml per contaglobuli, in polistirolo Ø 33 x 60 mm, tappo bianco naturale a pressione;
107037	30 ml polyethylene container, coulter counter TOA type; Ø 32 x 68 mm	Contentitore da 30 ml; in polietilene; Ø 32 x 68 mm per conta globuli tipo TOA,
109047	25 ml, polypropylene, faeces container; Ø 25 x 80 mm; with white screw cap and spatula	Contentitore da 25 ml, per feci, in polipropilene, Ø 25 x 80 mm, tappo bianco a vite con spatola,
109048	25 ml, polypropylene, faeces container; Ø 25 x 80 mm; with red screw cap and spatula; sterile A	Contentitore da 25ml, per feci, in polipropilene, Ø 25 x 80 mm; tappo rosso a vite con spatola, sterile A
109147	25 ml, polypropylene, faeces container; Ø 25 x 80 mm; with white screw cap and spatula; labelled	Contentitore da 25ml, per feci, in polipropilene, Ø 25 x 80 mm; tappo bianco a vite con spatola, etichettato
109148	25 ml, polypropylene, faeces container; Ø 25 x 80 mm; red screw cap and spatula; labelled; sterile A	Contentitore da 25ml, per feci, in polipropilene, Ø 25 x 80 mm; tappo rosso a vite con spatola, etichettato; sterile A
109247	25 ml, polypropylene, universal container, Ø 25 x 80 mm with white screw cap;	Contentitore universale da 25ml, in polipropilene, Ø 25 x 80 mm, tappo bianco a vite;
109248	25 ml, polypropylene, universal container, Ø 25 x 80 mm with red screw cap; sterile A	Contentitore universale da 25 ml, in polipropilene, Ø 25 x 80 mm, tappo rosso a vite; sterile A
109348	25 ml, polypropylene, faeces container; Ø 25 x 80 mm; with red screw cap and spatula; labelled; individually wrapped; sterile A	Contentitore per feci da 25 ml, in polipropilene, Ø 25 x 80 mm; tappo rosso a vite con spatola, etichettato; confezione singola; sterile A
109447	25 ml, polypropylene, universal container, Ø 25 x 80 mm with white screw cap; labelled	Contentitore universale da 25 ml, in polipropilene, Ø 25 x 80 mm; tappo bianco a vite; etichettato
109448	25 ml, polypropylene, universal container, Ø 25 x 80 mm with red screw cap; labelled; sterile A	Contentitore universale da 25 ml, in polipropilene, Ø 25 x 80 mm, tappo rosso a vite; etichettato, sterile A
109848	25 ml, polypropylene, universal container, Ø 25 x 80 mm, red screw cap; individually wrapped; sterile A	Contentitore universale da 25 ml, in polipropilene, Ø 25 x 80 mm, tappo rosso a vite; in confezione singola, sterile A
202037	60 ml universal container for human fluids (sputum etc), in polystyrene; Ø 60 x 34 mm; with detached white pressure cap	Contentitore universale per fluidi umani (espettorato etc), da 60 ml; in polistirolo; Ø 60 x 34 mm tappo bianco a pressione, separato;
202038	60 ml universal container for human fluids (sputum etc), in polystyrene; Ø 60 x 34 mm; with red pressure cap; sterile R	Contentitore universale per fluidi umani (espettorato etc), da 60 ml; in polistirolo; Ø 60 x 34 mm; sterile R tappo rosso a pressione,
206047	60 ml polypropylene, universal container; Ø 40 x 60 mm; with white screw cap	Contentitore 60 ml, in polipropilene, Ø 40 x 60 mm tappo bianco a vite,
206048	60 ml polypropylene, universal container; Ø 40 x 60 mm; with red screw cap; sterile A	Contentitore 60 ml, in polipropilene, Ø 40 x 60 mm; tappo rosso a vite, sterile A
206147	60 ml polypropylene, universal container; Ø 40 x 60 mm; with white screw cap; labelled	Contentitore 60 ml, in polipropilene, Ø 40 x 60 mm, tappo bianco a vite, etichettato
206148	60 ml polypropylene, universal container; Ø 40 x 60 mm; with red screw cap; labelled; sterile A	Contentitore 60 ml, in polipropilene, Ø 40 x 60 mm; tappo rosso a vite, etichettato; sterile A
206248	60 ml polypropylene, universal container; Ø 40 x 60 mm; with white screw cap; labelled; sterile A	Contentitore 60 ml, in polipropilene, Ø 40 x 60 mm; tappo bianco a vite, etichettato; sterile A
206348	60 ml polypropylene, universal container; Ø 40 x 60 mm; with red screw cap; labelled; individually wrapped; sterile A	Contentitore 60 ml, in polipropilene, Ø 40 x 60 mm; tappo rosso a vite, etichettato; in confezione singola; sterile A
206548	60 ml polypropylene, universal container; Ø 40 x 60 mm; with red screw cap; individually wrapped; sterile A	Contentitore 60 ml, in polipropilene, Ø 40 x 60 mm; tappo rosso a vite, in confezione singola, sterile A
206748	60 ml polypropylene, universal container; Ø 40 x 60 mm; with red screw cap; sterile R	Contentitore 60 ml, in polipropilene, Ø 40 x 60 mm; tappo rosso a vite, sterile R