



EC DECLARATION OF CONFORMITY

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

Test tubes and stoppers for samples of biological fluids from the human body

References:

- 4th and 25th groups as per Declaration according to D.Lgs. 332 submitted to the Italian Ministry of Health on 8/5/2001
- DIR 98/79 /CE acknowledged by Italy with D.Lgs. 332 of 08/09/2000
- Device Master Files: 02-20 - “Test tubes for in vitro diagnostic examination” and 02-17 - “Stoppers for test tubes”
- 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, fulfil the obligations imposed by the Directives, 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 Directives.

LP ITALIANA SPA keeps at the disposal of the Competent Authorities this Declaration of Conformity, together with the relative Device Master File (cod. FT 02-20) comprising the following documents.

Technical: <i>General product description including variants</i>	<i>Design information</i>
<i>Documentation of the Quality System</i>	<i>Technical drawings</i>
<i>Direction for use description</i>	<i>Risk analysis</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 test tubes:

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 test tubes 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 test tubes*
- *Immediate notification to the Competent Authorities of incidents involving the use of the test tubes, on learning of them.*

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

LP ITALIANA SPA
Legal Representative
(*Francesco Leopardi*)

Signed the, 25 May 2022



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 R.E.A. MI 882798
 Reg. Imp. C.F. e P.I. MI 01794050151

List Number:	DMF 02-20 Rev. 11	Date	2019.02.28
EC Declaration of Conformity:	"Test tubes for samples of human body fluids"		
Product classification:	IVD - "Other Device"		
EC Directive	98/79/CE		
Device Master File Nr	FT 02-20		

Product Code List

Code	Description 	Descrizione 
110118	20 ml Polystyrene cylindrical test tube without rim, Ø 16 x 150 mm sterile, with yellow stopper	Provetta cilindrica da 20 ml in polistirolo, Ø 16 x 150 mm, senza bordo, con tappo giallo, sterile R
110418	5 ml Polystyrene cylindrical test tube, Ø 12 x 75 mm, without rim, with yellow stopper, in bags of 250 pcs, sterile R	Provetta cilindrica da 5 ml in polistirolo, Ø 12 x 75 mm, senza bordo, chiusa con tappo giallo, in sacchetti da 250 pz, sterile R
111018	10 ml Polystyrene cylindrical test tube, Ø 16 x 100 mm, graduated at 2,5 - 5 - 10 ml, sterile, plugged with yellow stopper	Provetta cilindrica in polistirolo da 10 ml, Ø 16 x 100 mm, graduata a 2,5 - 5 - 10 ml, con tappo giallo, sterile R
111118	10 ml Clear Polystyrene cylindrical test tube, Ø 16 x 100 mm, graduated at 2,5 - 5 - 10 ml, sterile, plugged with yellow stopper, individually labelled	Provetta cilindrica da 10 ml in polistirolo, Ø 16 x 100 mm, graduata a 2,5 - 5 - 10 ml, con tappo giallo, etichettata singolarmente, sterile R
111148	10 ml Polypropylene cylindrical test tube, Ø 16 x 100 mm, graduated at 2,5 - 5 - 10 ml, with yellow stopper, sterile R	Provetta cilindrica in polipropilene da 10 ml, Ø 16 x 100 mm, graduata a 2,5 - 5 - 10 ml, etichettata, tappo giallo, sterile R
111548	15 ml Polypropylene test tube, Ø 17 x 120 mm, graduated up to 14 ml, with blue screw cap, sterile R	Provetta in polipropilene da 15 ml, Ø 17 x 120 mm, graduata fino a 14 ml, con tappo a vite blu, sterile R
112018	10 ml Polystyrene conical test tube, Ø 16 x 100 mm, graduated at 0,5 - 1 - 2,5 - 5 - 10 ml, plugged with yellow stopper, sterile R	Provetta conica da 10 ml in polistirolo, Ø 16 x 100 mm, graduata a 0,5 - 1 - 2,5 - 5 - 10 ml, chiusa con tappo giallo, sterile R
112118	10 ml Polystyrene conical test tube, Ø 16 x 100 mm, graduated at 0,5 - 1 - 2,5 - 5 - 10 ml, plugged with yellow stopper, labelled, sterile R	Provetta conica da 10 ml in polistirolo, Ø 16 x 100 mm, graduata a 0,5 - 1 - 2,5 - 5 - 10 ml, chiusa con tappo giallo, etichettata, sterile R
112918	10 ml Polystyrene conical test tube, Ø 16 x 100 mm, graduated at 0,5 - 1 - 2,5 - 5 - 10 ml, plugged with yellow stopper, individually wrapped, sterile R	Provetta conica da 10 ml in Polistirolo trasparente, Ø 16 x 100 mm, graduata a 0,5 - 1 - 2,5 - 5 - 10 ml, chiusa con tappo giallo, confezione singola, sterile R
113018	5 ml Polystyrene cylindrical test tube, Ø 12 x 92 mm graduated at 0,5 - 2,5 - 5 ml, plugged with yellow stopper, sterile R	Provetta cilindrica da 5 ml, in polistirolo, Ø 12 x 92 mm, graduata a 0,5 - 2,5 - 5 ml, chiusa con tappo giallo, sterile R
113118	5 ml Polystyrene cylindrical test tube, Ø 12 x 92 mm graduated at 0,5 - 2,5 - 5 ml, plugged with yellow stopper, labelled, sterile R	Provetta cilindrica da 5 ml, in polistirolo, Ø 12 x 92 mm, graduata a 0,5 - 2,5 - 5 ml, chiusa con tappo giallo, etichettata, sterile R
114048	3 ml Polypropylene cylindrical test tube Ø 12 x 51mm, flat bottom, graduated at 0,5 - 1 - 2 - 2,5 ml, plugged with yellow stopper, sterile R	Provetta cilindrica da 3 ml in polipropilene, Ø 12 x 51 mm, fondo piatto, graduata a 0,5 - 1 - 2 - 2,5 ml, chiusa con tappo giallo, sterile R
114148	3 ml Polypropylene cylindrical test tube Ø 12 x 51mm, flat bottom, graduated at 0,5 - 1 - 2 - 2,5 ml, plugged with yellow stopper, labelled, sterile R	Provetta cilindrica da 3 ml in polipropilene, Ø 12 x 51 mm, fondo piatto, graduata a 0,5 - 1 - 2 - 2,5 ml, chiusa con tappo giallo, etichettata, sterile R
115048	5 ml Polypropylene cylindrical test tube Ø 16 x 60mm, flat bottom, graduated at 1 - 2,5 - 5 ml sterile, plugged with yellow stopper	Provetta cilindrica da 5 ml in polipropilene, fondo piatto, Ø 16 x 60 mm, graduata a 1 - 2,5 - 5 ml, chiusa con tappo giallo, sterile R
115148	5 ml Polypropylene cylindrical test tube Ø 16 x 60mm, flat bottom, graduated at 1 - 2,5 - 5 ml sterile, plugged with yellow stopper, individually labelled	Provetta cilindrica da 5 ml in polipropilene, fondo piatto, Ø 16 x 60 mm, graduata a 1 - 2,5 - 5 ml, chiusa con tappo giallo, etichettata, sterile R
116048	50 ml Polypropylene test tube, Ø 30 x 115 mm, with blue screw cap, graduated, sterile R	Provetta in polipropilene da 50 ml, Ø 30 x 115 mm, graduata, con tappo a vite blu, sterile R
117018	3 ml Polystyrene cylindrical test tube Ø 12 x 56 mm, graduated at 0,5 - 1 - 2 - 3 ml sterile, plugged with yellow stopper	Provetta cilindrica da 3 ml in polistirolo, Ø 12 x 56 mm, in polistirolo, graduata a 0,5 - 1 - 2 - 3 ml, chiusa con tappo giallo, sterile R





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Code	Description 	Descrizione 
117118	3 ml Polystyrene cylindrical test tube Ø 12 x 56 mm, graduated at 0,5 - 1 - 2 - 3 ml sterile, plugged with yellow stopper labelled	Provetta cilindrica da 3 ml in polistirolo, Ø 12 x 56 mm, graduata a 0,5 - 1 - 2 - 3 ml, chiusa con tappo giallo, etichettata, sterile R
118548	15 ml Polypropylene test tube Ø 17 x 120 mm, graduated up to 14 ml, with blue screw cap, sterile, on expanded PS tray, 50 pcs, in sealed PE bag	Provetta in polipropilene da 15 ml, Ø 17 x 120 mm, graduata fino a 14 ml, con tappo a vite blu, su vassoio di Polistirolo espanso, in sacchetto di PE sigillato, sterile R
119548	15 ml Polypropylene test tube Ø 17 x 120 mm, graduated up to 14 ml, with blue screw cap, sterile R individually wrapped	Provetta in polipropilene da 15 ml, Ø 17 x 120 mm, graduata fino a 14 ml, con tappo a vite blu, confezione singola, sterile R