



LP ITALIANA SPA

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Milano, 30.07.2003

EC DECLARATION OF CONFORMITY

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

Plates or dishes for testing samples of biological fluids coming from the human body

References:

- Groups no. 13, 14, 15 as per Declaration according to DLL 332 submitted to the Italian Ministry of Health on 08/05/2001
- DIR 98/79 /CE acknowledged by Italy with DLL 332 of 08/09/2000
- Device Master File n. 02-13- "Plates for microbiology"

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 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 02-13) 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>Methods of manufacture</i>	<i>Labelling</i>

and assuring that the relative methods of manufacture follow the principles of quality assurance appropriate for these devices:

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 the use of plates and dishes 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 plates / dishes*
- *Immediate notification of the Competent Authority of incidents involving the use of the plates / dishes, on learning of them*

With the above, LP ITALIANA SPA notifies the Italian Ministry of Health to affix on the plates / dishes, subject of this Declaration, the CE marking of conformity in accordance to the Article 16 and Annex X of the mentioned Directive.

LP ITALIANA SPA

Legal Representative

(Francesco Leopardi)



Numero elenco:	02-13	Sheet 1/1
Dichiarazione di Conformità CE:	"Plates or dishes for testing samples of biological fluids coming from the human body"	
Classificazione del prodotto:	IVMDD - "Other Device"	
Direttiva di riferimento:	98/79/CE	
Fascicolo Tecnico Nr	FT 02-13	

Product Code List

Ref. Code	Variant Code	Description	Packaging (Q.ty per box)
Petri Dishes			
120018	-----	Ø65 mm – “contact” type - 10 in sealed PE bags; sterile R	1.000
122218	-----	Ø90 mm – 2 compartments - 20 in sealed PE bags; sterile A	480
122318	-----	Ø90 mm – 3 compartments - 23 in sealed PE bags; sterile A	552
124518	-----	Ø60 mm – 20 in sealed PE bags; sterile R	1.000
125518	-----	Ø80 mm – 10 in sealed PE bags; sterile R	480
122518	-----	Ø90 mm – 23 in sealed PE bags; sterile A	552
-----	122510	122518 Sterile R	552
121518	-----	Ø100 mm – 20 in sealed PE bags; sterile R	480
126518	-----	Ø120 mm – 10 in sealed PE bags; sterile R	200
127518	-----	Ø150 mm – 10 in sealed PE bags; sterile R	140
Clear Polystyrene 96-well Microtiter Plates (128 x 86 mm)			
120030	-----	U bottom; single wrapped	168
-----	120038	120030 Sterile R	168
120130	-----	V bottom; single wrapped	168
-----	120138	120130 Sterile R	168
129930	-----	Lid for 120030 – 120038 – 120130 – 120138; single wrapped	220
-----	129938	129930 Sterile R	220
Blood Grouping Plate and Rod			
120610	-----	10 seats plate; 20 in cardboard box	400
120110	-----	Container (bottom and lid) for 4 plates; 5in PS foam container and shrink film	20
132010	-----	Mixing rod for blood grouping	1.000