



LP ITALIANA SPA

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Milano, 04.06.2003

EC DECLARATION OF CONFORMITY

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

Cassettes for treatment of histology samples coming from human body

References:

- 16th group as per Declaration according to DLL 332 submitted to the Italian Ministry of Health on 08/05/2001
- DIR 98/79 /CEE acknowledged by Italy with DLL 332 of 08/09/2000
- Technical File n. 02-14 - "Embedding cassettes"

LP ITALIANA SPA

declares

that product from its catalogue, from which the following code **19102X**

(where X take the place of numbers, in order to form possible code variations)

fulfil

all obligations imposed by the Directive in reference to, and in particular the Essential Requirements of Annex I and

are not contained

within the list of **Annex II** of the Directive.

LP ITALIANA SPA keeps at the disposal of the Italian competent authorities this Declaration of Conformity, together with the relative Technical File (cod. FT 02-14) containing the following documents.

Technical:	<i>General product description and variations</i>	<i>Project information</i>
	<i>Quality System pertinent documentation</i>	<i>Risk analysis</i>
	<i>Technical drawings</i>	<i>Direction for use description</i>
	<i>Raw materials properties</i>	<i>Microbial conditions</i>
	<i>Performances and limits</i>	<i>Tests reports</i>
	<i>Production technology</i>	<i>Labelling</i>

and assuring that the relative production process fulfils the requirements of production quality assurance:

Production process 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 established and updates the procedure PO 04.03 covering the following aspects:

- *Systematic evaluation of the acquired experience in the use of cassettes*
- *Application of eventual corrective actions proportional to the level of risks connected with the use of the cassettes*
- *Immediate information of the Competent Authority following accidents relative to the use of the cassettes*

With the above, LP ITALIANA SPA informs the Italian Ministry of Health of placing on the cassettes, subject of this Declaration, the CE marking of conformity in accordance to the Article 15 c.2 of the reference Directive.

LP ITALIANA SPA
Legal Representative
(*Francesco Leopardi*)