



LP ITALIANA SPA

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EC DECLARATION OF CONFORMITY

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

Test tubes for samples of human body fluids

References:

- 4th group 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 Nr. 02-20- "Test tubes for in vitro diagnostic examination"
- Certified Quality Management System according to UNI EN ISO 9001:2008 - Nr LRC0110892/QMS
First issue: 12.04.2001 – Certificate Validity: 11.04.2013

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 02-20) 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:

Method 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 and Annex X of the mentioned Directive.

LP ITALIANA SPA
Legal Representative
(Francesco Leopardi)

Signed the, 21 SET 2011