LP ITALIANA SPA
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EC DECLARATION OF CONFORMITY

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

Tips and Pipettes for transferring samples of biological fluids coming from the human body

References:

- Groups no. 10, 20, 23, 24 as per Declaration according to DLL 332/2000 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. 02-07- "Serological pipettes, Pasteur pipettes, ESR pipettes, Tips for pipettors"
- 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 Nr 02 - 07, 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 02-07) comprising the following documents.

Technical:

General product description including variants
Documentation of the Quality System
Technical drawings
Characteristics of the basic materials
Performances and limits
Method of manfacture
Design information
Risk analysis
Direction for use description
Microbiological state
Tests reports
Labelling

and assuring that the relative method of manfacture follows the principles of quality assurance appropiate for these tips and pipetes:

Method of manfacture 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 the following aspects:

- *Reviewing the experience gained from tips and pipettes 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 tips and pipettes*
- *Immediate notification to the Competent Authotities of incidents involving the use of the tips and of the pipettes, on learning of them.*

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

LP ITALIANA SPA
Legal Representative
(Francesco Leopardi)

Digitally signed by Lazari Cristina
Date: 2018.12.19 15:45:11 EET
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA, mun. CHISINAU, IDNO 1013600060828, «BECOR» S.R.L., PENTRU CONTRACTE, SOCIETATEA CU RASPUNDERE LIMITATA

29 SET 2011

Signed the,