



EC DECLARATION OF CONFORMITY

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

24 hours urine containers

References:

- 1st group as per Declaration according to D.Lgs. 332 submitted to the Italian Ministry of Health on 08/05/2001
- DIR 98/79/CE acknowledged by Italy with D.Lgs. 332 of 08/09/2000
- Device Master File n. 02-05- "24 hours urine containers"
- 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 02-05, fulfil the obligation 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 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 02-05) 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>Methods of manufacture</i>	<i>Labelling</i>

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

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 24 hours urine containers 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 24 hours urine containers*
- *Immediate notification to the Competent Authorities of incidents involving the use of the 24 hours urine containers, on learning of them*

With the above, LP ITALIANA SPA notifies the Italian Ministry of Health to affix on the "24 hours urine containers", subject of this Declaration, the CE marking of conformity in accordance with article 16 (17) and Annex X of the mentioned Directives.

LP ITALIANA SPA



Legal Representative
(*Francesco Leopardi*)

Signed in Milan the, 12 May 2021



List Number:	DMF 02-05 Rev. 4	Date	2018.04.16	Sheet	1/1
EC Declaration of Conformity:	"24 hours urine containers"				
Product classification:	IVD - "Other Device"				
EC Directive	98/79/CE				
Device Master File Nr	FT 02-05				

Product Code List

Code	Description 	Descrizione 
108094	Disposable 24 hours urine container, in plastified cardboard with inner polyethylene bag, volume 2.5 l, dimensions 195 x 100 x 130 mm	Contentitore monouso per urine 24 ore da 2,5 l in cartoncino plastificato e sacchetto interno in polietilene; dimensioni 195 x 100 x 130 mm
108039	24 hours urine container, in high density polyethylene, with screw cap and spout, volume 2.5 l, Dimensions 255 x 100 x 100 mm	Contentitore urine 24 ore, in polietilene alta densità, con tappo a vite per riempimento e prelievo, volume 2.5 l, dimensioni 255 x 100 x 100 mm
108139	24 hours urine container, in high density polyethylene, with screw cap and spout, labelled, volume 2.5 l, Dimensions 255 x 100 x 100 mm	Contentitore urine 24 ore, in polietilene alta densità, con tappo a vite per riempimento e prelievo, etichettato, volume 2.5 l, dimensioni 255 x 100 x 100 mm
108230	24 hours urine container, in high density polyethylene, screw cap, volume 2 l, Dimensions 180 x 90 x 215 mm	Contentitore urine 24 ore in polietilene alta densità, con tappo a vite, volume 2 l, dimensioni 180 x 90 x 215 mm
108231	24 hours urine container, in high density polyethylene, screw cap, volume 2 l, individually packed and carry bag, Dimensions 180 x 90 x 215 mm	Contentitore urine 24 ore in polietilene alta densità, con tappo a vite, volume 2 l, confezione singola in cartoncino e sacchetto di trasporto; dimensioni 180 x 90 x 215 mm,