



International Certifications

# Certificate of Conformity

We confirm that the technical documentation for the below mentioned products (All the devices except devices for self testing and Annex II devices) according to the council Directive No. 98/79/EC

## Autoclaves and Sterilizers (For Laboratory use only)

(For detailed specification refer to Annexure of this certificate page 01)

Manufactured by the company

**Shivani Scientific Industries Pvt. Ltd.**

**Head Office: 16 Bhola bhagwan Ind. Estate, I.B Patel Road, Goregaon (East), Mumbai-40006,India.**

**Site Address: 26 A, Raju Ind. Estate, Penkar Pada Road, Near Dahisar Check Naka, Mira-401104, Mumbai, India.**

Complies with the applicable requirements of Directive No. 98/79/EC (Annex II, section 4 & 5).

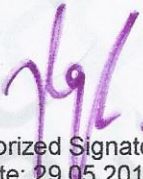
Referring to the intended use, the certification body has conducted with successful results the review of the manufacturer's technical documentation of the certified product according to the above mentioned directive and appropriate Harmonized European standards.

This certificate is issued under following conditions:

1. The manufacturer's technical documentation, as required for 'all devices except devices for self testing and Annex II devices', has been reviewed and found to comply with the requirements in Annex II, section 4 & 5.
2. It applies only to mentioned models of in-vitro devices/equipments.
3. The manufacturer is obligated to assured conformity of all the in-vitro devices/ equipments of the respective model to the type assessed by the means of this certificate.
4. Any significant changes in the design or processes used to manufacture the product/equipments, or the revision to the Directives or standards referred above may require special audit by EC International certifications.
5. After fulfilling the relevant EU legislation requirement the manufacturer shall affix to each in-vitro devices/equipment, of the above refer models, CE marking according to following example:



Certificate no: ECIC-2014-IVD-01  
Certificate Issue Date: May 29, 2014  
Certificate Expiry Date: May 28, 2017

  
Authorized Signatory  
Date: 29.05.2014



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Registered at: Office 23, Sagar Plaza, Kasarwadi, Pune, Maharashtra, India. [www.ecint.co.in](http://www.ecint.co.in)



International Certifications  
*Annexure to Certificate*

No. ECIC-2014-IVD-01

Issued for the company  
**Shivani Scientific Industries Pvt. Ltd.**

**Head Office:**  
16 Bhola Bhagwan Ind. Estate, I.B Patel Road, Goregaon (East),  
Mumbai- 400063, India.

**Site Address:**  
26 A, Raju Ind. Estate, Penkar Pada Road, Near Dahisar Check Naka,  
Mira- 401104, Mumbai,  
India.

List of the devices covered by the EC Certificate:

Autoclaves and Sterilizers			
Sr. No.	Brand	Model/ Variant	Range
01	Ketan	a) Vertical Portable	PA06,PA12,PA21,PA21S,PA6G,PA12G, PA21G, Size given by supplier
		b) Single Wall Semi & fully Automatic	SA35,SA52,SA111,SA178,FA35, FA52,FA111,FA178, Size given by supplier
		c) Double Wall Semi & fully Automatic with & without Vacuum	DW35,DW75,DW111.DW35S.DW75S.DW111S ,DW35V,DW75V,DW111V, Size given by supplier
		d) Front Loading Bench Top steam Sterilizer	FL17N, FL17B, Size given by supplier
		e) Horizontal Steam Sterilizer	HAC150,HAC175,HAC235,HAR180,HAR430, Size given by supplier
		f) Hot Air Sterilizer	HAS60,HAS120,HAS200, Size given by supplier



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