International Certifications

Certificate of Conformity

CE

Issued in compliance with the Directive No. 98/79/EC of the European parliament and of the council on in vitro diagnostic medical devices.

In Vitro Diagnostics Devices for Professional Use

Type: Laboratory Diagnostic Kits & Reagents

pH Kits, Vitality Kit, HOS Kit, Diff Quick Morphology, Anti-Sperm Antibody Detection Kit, Fructose Test, Haloview, Leukocye Kit, Zinc SFT Kit.

Manufactured by

"Shivani Scientific Industries Pvt. Ltd."

Head Office: 16, Bhola Bhagwan Ind. Estate, I.B. Patel Road, Goregaon (East), Mumbai – 400063, Maharashtra - India.
Site Address: 26A, Raju Ind. Estate, Penkar Pada Road, Near Dahisar Check Naka, Mira 401104, Mumbai India.

Compliance with the Essential requirement of the Directive No. 98/79/EC of IVD as amended, which apply to them.
EC International Certification performed an assessment of the technical documentation of the diagnostics medical devices in vitro in terms of intended use under the relevant sections of the above mentioned Directive and the relevant harmonized European standards: EN ISO 14971:2012, ISO 9001:2008, EN ISO 13485:2012, EN 15223-1:2012, EN 13612:2002, EN 13640:2008, EN ISO 18113-2:2011.

This certificate is issued under following conditions:
It applies only to the above model of in vitro diagnostics device. The manufacturer must ensure compliance of the specified models of the in vitro diagnostics device in accordance with this certificate. The certificate remains valid unless changes in technology, Quality system or the regulations invalidated it or at most until **October 2019**. After meeting the requirements of the relevant EU legislation, the manufacturer must identify every diagnostics medical device in vitro of the above models with the CE mark.

Certificate no: ECIC/IN/IVD/006-16
Certificate Issue Date: October 07, 2016
Certificate Expiry Date: October 06, 2019

INTERNATIONAL CERTIFICATIONS INDIA PUNE

Authorized Signatory
Date: 07.10.2016

Registered at: Office 23, Sagar Plaza, Kasarwadi, Pune, Maharashtra, India. URL: www.ecint.co.in