



International Certifications

CERTIFICATE OF CONFORMITY

Certificate No. : ECIC-IVD/08-22

Initial Issued Date : March 19, 2022

Certificate Expiry Date : March 18, 2025

Applicant (Name & Address) : PathnSitu Biotechnologies Pvt. Ltd.
PS Heights, 2nd Floor, Plot# A 28/1/11B/B, Road# 15
Nacharam IDA, Hyderabad 500 076, Telangana, India.

Manufacturing Site : PS Heights, 2nd Floor, Plot# A 28/1/11B/B, Road# 15
Nacharam IDA, Hyderabad 500 076, Telangana, India.

Product : 1) Caliber30 - Fully Automated IHC Staining System
2) MERSi - Multi Epitope Retrieval System

Complies with the requirements applicable to Directive 98/79/EC of IVD.

This is to certify that the technical documentation as required for the device has been reviewed and found to comply with the requirements and the relevant harmonized European standards: EN ISO 14971:2019, ISO 9001:2015, ISO 13485:2016, EN 15223-1:2016, EN ISO 18113-2:2011, EN 61010-2-101:2017, EN 61326-2-2:2021.

Any change of the Medical Device shall be immediately reported to EC INTERNATIONAL CERTIFICATIONS in order to examine validity of this certificate.

Certificate confirms that the product/equipment complies with the Essential Safety Requirements and Objectives of Mentioned Directive / Standard and refers to the sample(s) provided for testing / Certification.



Authorized Signatory

