



NO. 1 Cuizhu Street, Bldg 109, Hi-tech District, Zhengzhou City, Henan, China

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Statement Letter

September 20, 2025

We, **Henan Celnovte Biotechnology Co.,Ltd**, with registration address at NO.1 Cuizhu Street, Bldg 109, Hi-tech District, Zhengzhou City, Henan, China do hereby certify the following information:

1. We confirm that the Microstacker Flex Polymer Detection Kit SD5300 is fully compatible and suitable for use with the CNT 320 Fully Automatic Immunohistochemistry Stainer, even though the current Instructions for Use (IFU) explicitly mention compatibility only with the CNT 300/360 models.
2. The product is labeled with the IVD (In Vitro Diagnostic) mark, certifying its compliance with regulatory requirements for diagnostic use. It is intended for in vitro diagnostic applications.
3. The Microstacker Flex Polymer Detection Kit SD5300 has received approval from the U.S. Food and Drug Administration (FDA).
4. This product is designed and validated for use in Immunohistochemistry (IHC), Immunocytochemistry (ICC), and In Situ Hybridization (ISH) applications.
5. The Microstacker Flex Polymer Detection Kit SD5300, when used in conjunction with its associated antibody products, has successfully undergone and passed evaluation by NordiQC.

Sincerely,

Signed:

A handwritten signature in black ink, appearing to be "Hua Qi", written over a light grey rectangular background.

Name: Hua Qi

Title:CEO

HENAN CELNOVTE BIOTECHNOLOGY CO., LTD

