

Date: 2025/05/15

CONFIRMATION LETTER

To Whom It May Concern,

We, Datascope Corp., located at 15 Law Drive, Fairfield NJ 07004, USA hereby confirm that the medical device:

Intra-Aortic Balloon Catheter (IAB Catheter)
is manufactured at the following address:

- Address: 45 Barbour Pond Rd Wayne, NJ 07470 – as shown on CFS/ ISO.

However, the product label may show a different address:

- Address: 15 Law Drive, Fairfield NJ 07004 – as shown on the label, which refers to our legal manufacturing address where final packaging/distribution takes place.

This explanation is provided to clarify any potential discrepancy in documentation for regulatory purposes in Vietnam.

Sincerely,



Rama Hannineh

Regulatory Affairs Specialist

Datascope Corp.