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CE MARK and AUTHORIZED REPRESENTATIVE INFORMATION REMOVAL NOTICE

For Customers using i-STAT CK-MB and i-STAT BNP cartridges and associated control and calibration verification materials with the i-STAT 1 System

January 2026

Dear Valued Abbott Customer,

As part of Abbott's ongoing efforts to modernize the i-STAT System and align with evolving regulatory requirements, we are making labeling updates to the **i-STAT CK-MB** and **i-STAT BNP** cartridges and associated controls and calibration verification materials listed below:

Product Name	List Number/ Product Number	Product Name	List Number/ Product Number
<i>i-STAT CK-MB</i> cartridge	03P92-25	<i>i-STAT BNP</i> cartridge	03P93-25
<i>i-STAT CK-MB Control Level 1</i>	06P17-01	<i>i-STAT BNP Control Level 1</i>	06P17-05
<i>i-STAT CK-MB Control Level 2</i>	06P17-02	<i>i-STAT BNP Control Level 2</i>	06P17-06
<i>i-STAT CK-MB Control Level 3</i>	06P17-03	<i>i-STAT BNP Control Level 3</i>	06P17-07
<i>i-STAT CK-MB Tri Level Calibration Verification 1-3 Set</i>	06P17-04	<i>i-STAT BNP Tri Level Calibration Verification 1-3 Set</i>	06P17-08

For products included in the table above, the following labeling update will occur on May 26, 2026:

- The CE mark and associated Authorized Representative (EMERGO) information will be removed from the labeling, including the packaging and Instructions for Use (IFU), of the **i-STAT CK-MB** and **i-STAT BNP** cartridges and the associated control and calibration verification materials.

Impact of labeling update to you, as the customer:

- No action is required on your part, as labeling changes do not impact the safety, performance, or authenticity of the products.
- You may continue to use your current inventory as normal
- The product formulation, manufacturing process, and intended use remains unchanged.

We appreciate and thank you for your continued support of Abbott and Abbott products. Should you or any of the health care providers you serve have any questions regarding this information, please contact your local support representative.

i-STAT is for *in vitro* diagnostic use only.

i-STAT is a registered trademark of Abbott.

For complete intended use and product information, visit www.globalpointofcare.abbott.

11-2025-75 APOC i-STAT CK-MB and BNP Cartridge on i-STAT 1 CE Mark Removal – External Communication Letter