Urgent Field Safety Notice/001

U-Pette®, C-Pette®, H-Pette®

April 15, 2025

Attention: Laboratory Technician

The U-Pette™ C-Pette® and H-Pette® dispenser attaches to most popular brands of blood collection or other tubes with stoppers. Once inserted into the stopper they allow you to dispense drops onto test strips, analyzer cassettes, or slides.

Model numbers:

7626-540-000-9	7630-500-000-9	7625-540-000-9	7620-540-000-9
7626-500-000-9	7630-540-000-9	7625-500-000-9	7620-500-000-9

Description of Problem:

This product was originally placed on the market under the Directive 98/79/EC (IVDD). In the transition to Regulation (EU) 2017/746 (IVDR), the qualification as an IVD medical device was re-assessed. It was determined that the U-Pette®, C-Pette® and H-Pette® do not qualify as IVD medical devices and thus should not carry the CE mark. Because the regulation change happened at the period ending the Pandemic the documentation and labeling was missed in updating and some product made it to the market with CE marking that should not have been CE marked.

Advise on Action to Be Taken by the User:

- These devices can be identified by the model numbers shown above.
- A recall of the devices that were CE marked in error has been initiated with sales channels.
- These devices do not need to be destroyed or disposed, they can be used as a non CE marked general laboratory equipment at the discretion of the user. However, these items do not currently comply with regulatory requirements for IVD medical devices.
- Recall was initiated April 15, 2025 of any CE marked items and all these incorrectly marked products should be removed from sales channels before May 31, 2025

Transmission of this Notice

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Company Contact:

Quality Assurance, Labcon

www.labcon.com/problemreport.html

Email: custsupport@labcon.com

3700 Lakeville Highway, Petaluma, CA 94954 USA

Confirmation:

This notice has been filed with the appropriate authorized agency. The undersigned confirms that this notice has been filed with the appropriate regulatory agency.

Tom Moulton,

Labcon