

FDA Letter to US Health Care Providers Regarding Getinge's Cardiosave, Cardiohelp and HLS Set Devices

This letter is intended for an audience outside of the US

Dear Valued Customer:

On May 8th, the US Food and Drug Administration (FDA) published a letter to US health care providers on their website, alerting them about safety and quality concerns of Getinge's Cardiosave Intra-Aortic Balloon Pump (IABP), Cardiohelp System and HLS Set Advanced. The safety and quality concerns are related to previously communicated recalls. The FDA is recommending that US health care facilities transition away from use of the devices and seek alternatives if possible.

It is important to note that the FDA is only providing guidance to US Health Care Providers and the situation in the US has key differences with most other regulatory regions:

- As a resolution to several of the Cardiosave Field Safety Corrective Actions (FSCAs), Getinge began deploying the D.00 software update in late 2022 and more recently the D.01 update. These updates are currently unavailable in the US.
- As a resolution to the HLS and PLS Set packaging FSCAs, Getinge completed design and validation of new packaging. Supporting evidence for the HLS-Set was submitted to our Notified Body in April followed by the submission of the PLS-Set in May (see separate letter for more detail). The US approach is still under discussion with the FDA.
- Deployment of all Cardiohelp console corrections are either completed or underway in the field.

Getinge is pausing marketing of Cardiohelp and Cardiosave in the US and limiting sales to customers who have no other options. For markets outside of the US where Getinge has implemented product improvements we will continue to sell Cardiosave and Cardiohelp and continue to provide intra-aortic balloon catheters and HLS Sets in markets where they are permitted and approved for use.

Getinge will continue to take important steps to correct quality-related deficiencies and accelerate innovation. At the same time, Getinge has accelerated the development of the next generation of the Cardiohelp and Cardiosave IABP hardware.

We will provide regular updates on progress.

Best Regards,

MD Country

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