

## **TÜV SÜD suspends CE-certificate for Getinge's Cardiosave**

Dear valued customer,

We regret to inform you that the notified body, TÜV SÜD, has issued a suspension of the CE certificate for the Cardiosave Intra-Aortic Balloon pumps for up to three months, based on concerns related to risk management, post market surveillance and vigilance, as well as information pertaining to field safety corrective actions. Getinge has been given until June 24<sup>th</sup>, 2023 to adhere to the required corrective actions and is fully committed to this date.

Effective immediately, Getinge cannot sell Cardiosave to any country requiring CE mark. Pumps already on the market can continue to be used and devices already in distribution can be delivered. Balloons and spare parts are not affected. Any on-going field safety corrective actions will continue as planned.

We would like to reiterate that the concerns from TÜV SÜD are solely about the risk management, post market surveillance and vigilance of the pump, as well as information pertaining to field corrective actions. However, we are continuously monitoring and implementing solutions that will make our products safer for patients.

Getinge appreciates the challenge this may pose to healthcare providers especially given our ongoing supply constraints. However, we are urgently working to resolve the situation as quickly as possible and really appreciate your ongoing patience and support. Please accept our sincere apologies.

Yours sincerely,



Avril Forde

Vice President Northern Europe