



## King Systems Receives FDA Warning Letter

King Systems – owned by Ambu A/S – has received a Warning Letter from the U. S. Food and Drug Administration (FDA) relating to an inspection of the King Systems manufacturing site in Noblesville, USA. The Warning Letter references King Systems' reply to the inspectional observations left by the FDA at the conclusion of the inspection.

The Warning Letter primarily addresses the timeline for validation of manufacturing processes for some legacy products. All new products and processes launched in the past 2.5 years have been validated, so this observation applies to retroactively validating the legacy processes. The Warning Letter is not expected to have consequences for products on the US market and little, if any, in other markets.

King Systems and Ambu take the request from FDA very seriously and has replied to FDA's Warning Letter on October 21, 2013. This is part of the efforts to bring the aforementioned processes to a higher standard than ever before.

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Since 1937, breakthrough ideas have driven our work to bring efficient healthcare solutions to life within our fields of excellence: Anaesthesia, Patient Monitoring & Diagnostics and Emergency Care. Millions of patients and healthcare professionals worldwide depend and rely on the functionality and performance of our products. We are dedicated to improving patient safety and determined to advance single-use devices. The manifestations of our efforts range from early inventions like the Ambu bag and the legendary Blue Sensor® electrodes to our latest landmark solutions such as the aScope™ – the world's first single-use videoscope. Our commitment to bringing new ideas and superior service to our customers has made Ambu one of the most recognised medical companies in the world. Our head office is situated in Ballerup near Copenhagen. Ambu has more than 2,200 employees in Europe, North America, Asia and the Pacific region. You can find more information about Ambu on our website: [www.ambu.com](http://www.ambu.com).