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To whom it may concern

We herewith would like to inform you about ongoing investigations carried out in cooperation with Swissmedic, Swiss Federal Office of Public Health, Swissnoso and the hospital with regard to a newly identified infection risk relating to cardiac surgery patients. In the context of this investigation Sorin has been informed that a Swiss hospital has experienced 6 cases (2 resulting in death) of severe infections after cardiac implant surgery (2008 – 2012). All such infections involved slow growing nontuberculous mycobacteria in patients who underwent open-heart surgery.

Whereas the root cause of the infection is still under investigation, some potential contamination sources of *Mycobacteria* in cardiac surgery procedures have been identified. One of the possible sources are heater cooler devices that are operated with tap water. Sorin takes the on-going investigations very serious and is cooperating both with Swissmedic, Swiss Federal Office of Public Health, Swissnoso and the hospital where an in depth investigation is actually carried out.

In coordination with Swissmedic, Sorin will inform its customers with the enclosed "Important Information Letter" about this potential infection risk and measures to be observed to efficiently reduce the risk of infections. It should be noted that the newly identified risk of *Mycobacteria* infections is unlikely to be linked to a specific cause, but seems more likely to be a new concern to consider in the management of hospital hygiene, monitoring and cardiac surgery practices.

We trust, that this meets your expectations and we are obviously open to render any additional information you might deem helpful.

Sorin confirms its continued commitment to the highest standards of quality assurance.

Yours very truly



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