Notification regarding repair of products of former Kimura Medical Instrument Co., Ltd.

As a Market Authorization Holder (hereinafter referred to as MAH), we have succeeded Market Authorization regarding products manufactured and distributed by former Kimura Medical Instrument including artificial respirators and anesthesia machines, and as a medical equipment repair company, we accept requests of repair and maintenance of products manufactured by the former Kimura Medical Instrument.

As the said products fall under a category of medical equipment requiring specialist maintenance and management, in a case that any repair company other than us repairs such products, such company is required to make a notice to MAHs in advance based on Article 191 of Pharmaceuticals and Medical Equipment Law Enforcement Regulations (Former Pharmaceutical Affairs Law.) It includes precautions regarding repair of medical equipment requiring specialist maintenance and management (such as information about appropriate replacements for repair parts) and such information is updated on a daily basis and consolidated at us as an MAH. Therefore, it is a significantly important regulation requiring repair companies to make notification to MAHs in advance since such repair companies are also required to perform repair work based on recognition of updated precautions.

However, we have not received any notification regarding repair of the above-mentioned medical equipment from any repair company at least for the past three years. Therefore, if the above-mentioned medical equipment was repaired by anyone other than us during the period, it is likely that appropriate repair has not been made and we consider that use of such medical equipment may cause extremely dangerous situation.

Even though we are not responsible for any repair performed by other companies (it is natural that we are not responsible also for illegal repair), we deeply regret that such illegal companies are going about. Therefore, we have determined to take strict measures for such illegal repair companies in cooperation with the government. For these reasons, it is quite convenient for us if anyone who knows about any case like those described above may inform us such information.

(Even though notification in advance is supposed to be unnecessary for a slight repair according to the regulations above, the slight repair is considered to be limited within a range that doesn't require updated precautions for repair (such as replacing of consumable items or equivalent.))

That's all.