KEISEI MEDICAL INDUSTRIAL CO., LTD.

☐ Head Office 19-6, 3-chome,Hongo,Bunkyo-ku,Tokyo 113-0033,Japan TEL +81 3-3816-5851
☐ Niigata Plant 96, Yoshida-Konosu, Tsubame-shi, Niigata 959-0261,Japan TEL +81 256-92-3582

Urgent Field Safety Notice

Commercial name of the affected product: Air Fluidized Support System LI-7 Standard Type
FSCA-identifier: 8/11/2019
Type of action: the return of a MEDICAL DEVICE to the supplier

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Date: 13/11/2019

Attention:

Details on affected devices: Air Fluidized Support System LI-7 Standard Type
Serial No.1806001

Description of the problem:
The device is an air flux bed, supporting patients of burn injury, bedsores, or severe injury with floatation, applying physical principle of fine solid particles flux, consisting of a particle chamber which contains fine solid particles and a power department which supplies air to air chamber nearby the particle chamber through an air diffuser panel.
Keisei Medical Industrial has been decided the device as Class Ⅰ, applying RULE 12 of invasive devices “all other active devices” from a classification chart of MEDDEV because the device is intended neither to cure illnesses and injuries itself nor to supply or exchange energy to a patient.
However, the Czech authority notified us through the document that the device is classified as Class IIb, according to Classification Rule 9 in MEDDEV which regards an active therapeutic device which administer or exchange energy in potentially hazardous way as Class IIb. This decision was made because the device can be adjusted to a temperature of 40 °C , which can have serious thermal consequences for the patient, especially who are incapable of communicating or reacting in any way, in the event of their body being covered with a blanket.
Keisei Medical Industrial understood what the document says, and decided to recall our products.

Advise on action to be taken by the user:
The devices are recalled by our dealer ALTEC directly picking up them at the hospitals.

Transmission of this Field Safety Notice:
Please transfer this notice to other persons within your organisation or other organisations on which this action has an impact. We request that the details of any affected devices that have been transferred to other organisations be supplied to Keisei Medical Industries Co. Ltd. and for a copy of this Field Safety Notice to be passed on to the organization to which the device has been transferred

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Please complete & return the attached acknowledgement of receipt form and maintain awareness on this notice and related actions.

Contact reference person:

Junya Ohyama
Manager
KEISEI MEDICAL INDUSTRIAL CO.,LTD.
19-6,3-chome, Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
Tel: +81 3-3816-5851
e-mail: johyama@keiseimed.com

The undersigning person confirms that this notice has been notified the appropriate Regulatory Agency
(Closing paragraph)
Signature

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Subject: Field Safety Notice acknowledgement of Receipt

Dear sir and madam,

This is to confirm acknowledgement of the receipt for a Field Safety Notice.

We thank you in advance for your cooperation, and ask that you please complete and return this document to your local Czech representative or via one of the following option:

Fax: +81 3-3816-2941
Email: johyama@keiseimed.com

ACKNOWLEDGEMENT OF RECEIPT:
I acknowledge receipt of Field Safety Notice issued by KEISEI MEDICAL INDUSTRIAL Co.,LTD.

I understand the notice and have shared it with all applicable associates.

Name, Surname:

Hospital(s):

Signature:

Date: