

URGENT FIELD SAFETY NOTICE: MERIVAARA CHILD COTS

FSN type: New 17.09.2024 (First version issued)

Manufacturer:
Merivaara Corporation (SRN: FI-MF-000001175)

The product covered by the notice:
**Merivaara Child cots
(Child cot 385 and older models)**

For attention of:
Healthcare organization using the product, hospital.

[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]



This urgent Field Safety Notice concerns all **Child cots (Child cot 385 and older models) manufactured by Merivaara Corporation**. The manufacturer of the device can be checked from the labels of the frame or from the type plate (In model Child cot 385, the type plate is located below the sleeping surface).

In post-market surveillance, Merivaara Corporation has become aware of situation where the side rails of Merivaara's child cots have stayed in a raised position without locking in place. As a responsible medical device manufacturer, Merivaara wants to inform users about this matter.

If the side rail stays in the raised position without locking in place, it can fall down unexpectedly under a light load. This creates a serious risk of injury due to the risk of a patient falling.

The instructions for use of the devices include an instruction to always ensure the locking of the side rails to the desired position when adjusting them. When the user follows these instructions, it is acceptable and safe to continue using the devices. **Merivaara asks the healthcare organization to inform the users of the device about this Field Safety Notice and to pay attention to the safety matters mentioned in it.** A copy of this Field Safety Notice should be stored with the user instructions of each device covered by the notice.

This Field Safety Notice should be provided to all people in your organization who need to be aware of it. If the ownership of the device has been transferred to another organization, this notice must be provided to the organization that currently owns the device.

The manufacturer asks the user to reply to this notice using the Customer reply form at latest by 17.10.2024. The form will be sent with this notice.

Attachments:

FSN_Merivaara Child cot 385 and older models_Field Safety Notice_Customer reply form_149451_en.pdf

For questions concerning this notice, please reply to the delivery email or regulatory@lojer.com.

The Competent Medical Device Authority has been informed about this communication to customers. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority, as this provides important feedback regarding device safety.