

## Risk of entrapment of "big children" in medical bed rails

### Notice to manufacturers

The "big children" are children, who are too big to be lying in a classical child cot with bars, but their morphology does not yet correspond to that of an adult (size <146cm). These are children aging 3 to 11 years or equivalent morphology. These children have one major particular risk of trapping in the side rails of their medical bed. Several fatalities with big children found hanging in a position between the bars of the side rails were Afssaps reported.

It is therefore necessary to include in the initial design and development of the bed the specific needs of these "big children". Therefore Afssaps, after consultation with professionals and the National Commission for medical safety devices, communicates to manufacturers the following elements :

#### **Identified needs for the bedding of these "big children":**

1 – bed side rails that do not prevent the child to get out of bed voluntarily with the following characteristics:

- The space between bars (or two structural elements) is less than or equal to 65 mm<sup>1</sup>

- The space between the mattress and the bottom of the side rails is less than or equal to 65 mm

The dimension of 65mm corresponds to the requirement of the standard for 'child cot with bars' NF EN 716-1 and -2. The compliance should be tested according to the method given by this same standard (applying a force of 30N minimum)

2 – 'Closed' beds for big children whose disability does not allow them to get out of bed on their own, with the following characteristics:

- A perimeter is closed by side rails preventing from getting out of bed (without horizontal bars to prevent any scale effect),

- The space between bars (or between two structural elements) is less than or equal to 65 mm.

This dimension corresponds to the requirement of the standard for 'child cot with bars' NF EN 716-1 and -2. The compliance should be tested according to the method given by this same standard (applying a force of 30N minimum)

---

<sup>1</sup> This dimension of 65mm is coherent with the decision of the Sanitary Policy Decision dated 30.07.2008 about 'child cots with bars'. The existing benchmarks are:

- NF EN 716-2, 2008 "Beds with fixed cradle and domestic folding bed for children": the diameter of openings, spaces between elements of structure, should range between 45 mm (without added strength) and 65 mm (under a force of 30N)

- Nordic Requirement Specification - Adjustable beds for disabled children, "2001: the largest dimension in at least one direction between elements within the perimeter of the side rails / handle / side of the bed, in all normal positions of use, must be ≤ 60 mm, under a force of 30N. To avoid trapping fingers, distance between two moving parts must be either less than 4 mm or greater than 25 mm.

- Standard NF EN 12182, 1999 "Technical aids for disabled persons' safety distance between moving parts for children. To avoid any head trapping: less than 60mm or more than 300mm. To avoid finger trapping: less than 4 mm by 25 mm.

## **Safety criteria for design of appropriate side rails for the "big children":**

Bed side rails intended to "big children" (children size <146cm) meet at least the following criteria:

- The space between bars (or two structural elements) is less than or equal to 65 mm
- The space between the mattress and the bottom of the side rails is less than or equal to 65 mm

The compliance is tested according to the method given by the standard NF EN 716-2 (applying a force of 30N minimum).

These safety criteria may be confirmed shortly as part of a Sanitary Policy Decision.

The design of secure beds, in addition to these characteristics, must take into account the state of the art, applicable standards, risk analysis of the Manufacturer <sup>2</sup>

There is currently no legislative repository suitable for designing a side rail completely safe for big children. The competent French authorities seized the European Commission in order to launch European standardization work. In the meantime, I inform you of the existence of a document called "Nordic requirement specifications" worked out in 2001 by institutes dependent on the Ministries of Health and Social Affairs of the Nordic countries, which is an adaptation of the standard NF EN 1970 for "big children". This document gives a set of dimensional requirements for the design of side rails for older children, including limiting the space between the bars compatible with the characteristics listed above.

The manufacturer shall indicate which bed model (s) its side rail is compatible with.

If these safety requirements are met by the use of accessories, the manufacturer's analysis risks, ensure that its accessory:

- Is compatible with models of side rails such as claimed
- Does not create new risks of capture by its deformability, its own spaces, its fastening system
- Secures not only the space between the bars but also the space under the side rail, between the mattress and the lower bar
- Does not affect the hygiene of the sleeping surface
- Allows a good view of the bedridden child so that surveillance is not affected.

### **Claims for sleeping devices:**

The manufacturer clearly indicates the claims of their devices in the user manuals:

- Population (adult, child, size limit ...)
- Compliance with applicable standards (to be specified)

<sup>2</sup> *This clarification means that the limit of 65mm is not by itself a sufficient criterion to design a bed completely suitable for big children.*