



MedViron Compliant with FDA Bassinet Rule

Zeeland, MI: On Monday, December 19, 2016 the FDA issued a rule and special controls governing pediatric medical beds and medical bassinets that went into effect January 18, 2017. Prior to 12/19/16, medical bassinets were in the FDA classification “pediatric hospital bed”. This new rule creates *“a separate regulation, under § 880.5145, for medical bassinets and imposes special controls for this device type to provide a reasonable assurance of safety and effectiveness”*.

The FDA has ruled that the use of medical bassinets outside of traditional health care settings will be limited to prescription use. This means that our bassinets are intended to be sold to and for use by professionally licensed staff and facilities caring for the labor and delivery of children. Our bassinets are not intended for consumer sales unless prescribed by a doctor.



The new special controls for bassinets are:

(1) The manufacturer must conduct performance testing to determine material compatibility with cleansing products labeled to clean the device. Testing must demonstrate that the cleaning instructions provided by the manufacturer do not cause crazing, cracking, or deterioration of the device;

Cleaning product material compatibility testing fulfilling this control was completed and documented on 12/18/13, 12/23/14, and 7/1/15. Test data available upon request.

(2) Manufacturers shall conduct performance testing to ensure the mechanical and structural stability of the bassinet under expected conditions of use, including transport of patients in the bassinet. Testing must demonstrate that failures such as wheel or caster

breakage do not occur and that the device does not present a tipping hazard due to any mechanical failures under expected conditions of use; and

Performance testing fulfilling this control was completed and documented on 5/15/15. Test data available upon request.

(3) Each device must have the following label(s) affixed:

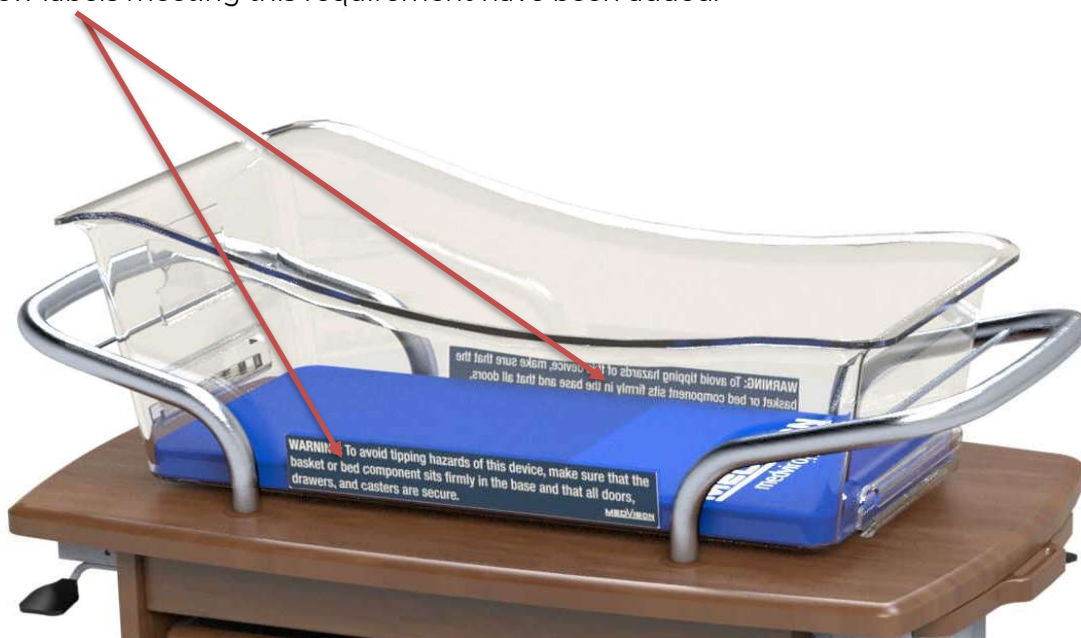
(i) Adequate instructions for users to care for, maintain, and clean the bassinet; and

An additional label for specific instruction for cleaning the plastic tubs was added. These instructions are already detailed in the operation and maintenance manual. The cleaning label is located on the bottom of the tub and is visible through the clear tub when the mattress is removed.

(ii) A warning label on at least two sides of the plastic basket or bed component with the following language in text of at least 9 millimeters in height:

WARNING: To avoid tipping hazards of this device, make sure that the basket or bed component sits firmly in the base and that all doors, drawers, and casters are secure.

New labels meeting this requirement have been added.



Additional information is available in the Federal Register:

[General Hospital and Personal Use Devices: Renaming of Pediatric Hospital Bed Classification and Designation of Special Controls for Pediatric Medical Crib; Classification of Medical Bassinet](#)