

To whom it may concern:

This letter is to certify that Cartstrong bassinets are listed with the United States (US) Food & Drug Administration (FDA) and comply with applicable standards for [21 CFR 880.5140](#) Pediatric Medical Crib and the special controls established for these class II devices as defined by the 12/19/16 final rule, effective January 18, 2017.

Device Listing - D291909

Registration - 1005432

This document includes support information pertaining to the “[special controls](#)” of this amendment.

- 1) Provide adequate instructions for users to care for, maintain and clean the device (including instructions that will not cause crazing, cracking or deterioration of the device)
- 2) The Mattress must meet the Consumer Product Safety Commission Standard for Flammability (16 CFR parts 1632 and 1633)
- 3) Ensure structural stability for expected use including transport for patients; ensuring no caster failures or tipping hazards.
- 4) Each device MUST include the following label, text 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.

- 5) Labeling must include adequate instructions for users to care for and maintain their bassinet.

Cartstrong Bassinets are manufactured in North America and carry a 5 year warranty. If you have any additional questions, please don't hesitate to contact me.

Thanks,

Angie Strongitharm
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