IRISH MEDICINES BOARD
SAFETY NOTICE

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EMS Medical Neonatal & Paediatric Endotracheal Tube Clamp / Holder

IMB Safety Notice: SN2012(13)
Circulation Date: 24 August 2012

MANUFACTURER/SUPPLIER
EMS Medical

TARGET GROUPS
Hospital CEOs
Maternity Units
Paediatric Units
Midwives
Risk Managers
Procurement Managers
Loan Store Managers
Clinical Engineers

ISSUE
The composition of the plastic used to make the clamp/holder was changed to a DEHP-free material. This affected the physical properties of these components, resulting in an increased risk of slippage or tube obstruction. EMS Medical went into administration over one year ago before this issue was identified.

The IMB included a copy of MDA/2012/049 in the July monthly mailing. At that time it was not known if there were any affected devices on the Irish market. The IMB now believe that some devices were supplied to Irish customers.

ACTION OR RECOMMENDATIONS
The IMB advises healthcare professionals/users to:

1. Ensure the appropriate personnel are made aware of this notice.
2. Identify, do not use and dispose of affected devices.
3. Inform the IMB if you have affected devices at your institution.

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ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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