



ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ

ΣΥΜΦΑ

Ιατρικές Υπηρεσίες και Υπηρεσίες Δημόσιας Υγείας
Αρμόδια Αρχή Ιατροτεχνολογικού Εξοπλισμού

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Θέμα: Ανακοίνωση σχετικά με τα προϊόντα που περιέχουν παραφίνη

Η Αρμόδια Αρχή Ιατροτεχνολογικού Εξοπλισμού, σας ενημερώνει για τους κινδύνους που ενδεχομένως να έχουν τα προϊόντα που περιέχουν παραφίνη όταν έρχονται σε επαφή με επιδέσμους, ρούχα, κλινοσκεπάσματα και επιθέματα, σύμφωνα με πληροφορίες που λήφθηκαν από την Αρμόδια Αρχή του Ηνωμένου Βασιλείου. Παρατίθεται αυτούσια η ανακοίνωση:

"Paraffin containing dermatological products – fire hazard in contact with dressings, clothing and bedding

Due to recent fatalities European Competent Authorities are now requesting that manufacturers review the warnings on their packaging and in the instructions for use in light of the essential requirements and to consider adding a warning for all topical products containing paraffin.

Bandages, dressings, clothes and bedding in contact with topical Paraffin based products are easily ignited with a naked flame. While some Paraffin containing dermatological products are regulated as medicines, others are regulated as medical devices. The same risks apply irrespective of regulatory regime. The manufacturer should consider whether their product meets the essential requirements of the Medical Device Directive in particular Article 3 of MDD 93/42/EEC, as amended, specifically Annex I, 13. The addition of the following warning under a section on warnings or risk should be considered:

‘This product can be absorbed by dressings, clothing and bedding, after which these fabrics can be easily ignited with a naked flame. Anyone using or handling this product should keep away from fire, until any skin or clothing which have come into contact with the product has been adequately cleaned.’

This issue has been discussed at the EU Vigilance Teleconference and as a result Designating Authorities are also writing to their Notified Bodies who may be involved in the certification of medical devices containing paraffin. We recommend you consider this potential fire hazard risk in your review of manufacturers’ technical documentation and product information, including labelling and instructions for use. In which case you should ensure manufacturer compliance with Article 3 of MDD 93/42/EEC, as amended, specifically Annex I, 13.

Thank you for your help in this matter."

Νικόλας Νικολάου

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