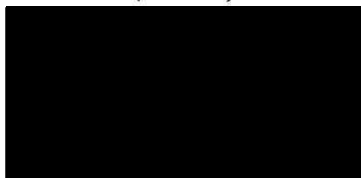


Nujno varnostno obvestilo
Urgent Field Safety Notice –

Address (*naslov*):



Sales Division
Lohmann & Rauscher GmbH & Co.KG
Westerwaldstr. 4 · D-56579 Rengsdorf
T:+43 316 67300025 / Fax:+43 316 682345
Email: Hannes.Schober@at.LRmed.com

Date: 16.11.2022

Nujno varnostno obvestilo

Urgent Field Safety Notice

**Odpoklic izdelka zaradi puščanja tesnilnega šiva primarne embalaže (nesterilnost)
Vliwaktiv® vpojna obloga z aktivnim ogljem, REF 20254 & 20255**

*Product Recall due to leaking seal seam of primary packaging (insterility),
Vliwaktiv® Absorbent activated charcoal dressing, REF 20254 & 20255*

Spoštovani,

Dear Sir or Madam,

Danes vas moramo obvestiti o previdnostnem odpoklicu izdelka Vliwaktiv® vpojne obloge z aktivnim ogljem zaradi možne nesterilnosti, ki jo povzroča puščanje tesnilnega šiva primarne embalaže.
Today, we have to inform you about the precautionary product recall of Vliwaktiv® Absorbent activated charcoal dressing due to a possible insterility caused by a leaking seal seam of the primary packaging.

Izdelki te serije, na katere je vplivala ta napaka smo dali takoj v karanteno našega skladišča.
The products of this lot affected by this defect were immediately quarantined in our warehouse.

Med notranjim preverjanjem kakovosti je bilo odkrito morebitno puščanje tesnilnega šiva. Izdelek bi lahko bil nesterilen zaradi morebitnega puščanja tesnilnega šiva primarne embalaže. To lahko privede do vnetij in/ali okužb, npr. kadar se izdelek uporablja na ranah. Zaenkrat s trga nismo prejeli nobenih dokazov/pri-
tožb o vnetjih ali okužbah.
During internal quality checks, the potential leakage of the seal seam was discovered. The product could be unsterile due to the potential leakage of the seal seam of the primary packaging. This could lead to inflammations and/or infections, e.g. when the product is used in wounds. So far, we have not received any evidence/complaints from the market about inflammations or infections.

Prosimo, da izdelke, ki jih imate na zalogi, vrnete preko priloženega obrazca. Izdelke seveda brezplačno zamenjamo ali po želji izstavimo dobropis.
Please return the products you have in stock using the enclosed form. The products will, of course, be exchanged free of charge or credited on request.

Prosimo, da v vaši organizaciji zagotovite, da so vsi uporabniki spodaj navedenih izdelkov in druge osebe, ki jih je treba obvestiti, seznanjeni s tem nujnim varnostnim obvestilom in nam pošljite izpolnjeno priloženo potrditev.
Please ensure in your organisation that all users of the products listed below and other persons to be informed are aware of this Urgent Field Safety Notice and return the enclosed confirmation to us completed.

Če ste izdelke posredovali tretjim osebam, jim posredujte kopijo teh informacij.
If you have passed on the products to third parties, please forward a copy of this information to them.



Vnaprej se vam zahvaljujemo za sodelovanje in se opravičujemo za morebitne nevšečnosti.
We thank you in advance for your cooperation and apologize for any inconvenience.

Z najlepšimi pozdravi,
With best regards,

Lohmann & Rauscher GmbH
i.V. / On behalf of

i.V. / On behalf of

16.11.2022
LRA-Graz

Hannes Schober
Regional Vigilance Officer

Priloga:

Attachment:

- 1) Nujno varnostno obvestilo / Odpoklic izdelka zaradi puščanja tesnilnega šiva primarne embalaže (nesterilnost) Vliwaktiv® vpojna obloga z aktivnim ogljem, REF 20254 & 20255
Urgent Field Safety Notice / Product Recall due to leaking seal seam of primary packaging (insterility), Vliwaktiv® Absorbent activated charcoal dressing, REF 20254 & 20255

Priloga 1
Enclosure 1

Nujno varnostno obvestilo
Urgent Field Safety Notice

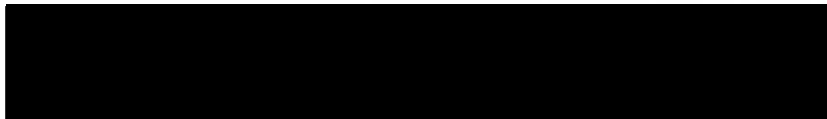
Datum: 16.11.2022

Odpoklic izdelka zaradi puščanja tesnilnega šiva primarne embalaže (nesterilnost)
Vliwaktiv® vpojna obloga z aktivnim ogljem, REF 20254 & 20255
Product Recall due to leaking seal seam of primary packaging (insterility),
Vliwaktiv® Absorbent activated charcoal dressing, REF 20254 & 20255

via Fax to LR: 0043-316 682345, E-mail: tea.borsic@LRMed.com

Pošiljatelj:
Sender: Lohmann & Rauscher GmbH & Co. KG / LR-SLO
Westerwaldstr.4
D-56579 Rengsdorf

Naslovnik:
Addressee:



Opis: **Odpoklic izdelka zaradi puščanja šiva primarne embalaže (nesterilnost),**
Description: **Vliwaktiv® vpojna obloga z aktivnim ogljem, REF 20254 in 20255**
Product Recall due to leaking seal seam of primary packaging (insterility),
Vliwaktiv® Absorbent activated charcoal dressing, REF 20254 & 20255

Korektivni ukrepi:
Corrective Actions:

Prosimo, da prizadetih izdelkov Vliwaktiv® vpojne obloge z aktivnim ogljem ne uporabljate več.
Please do not use the affected products of Vliwaktiv® Absorbent activated char. dressing anymore.

Prosimo, obvestite vse zaposlene, ki uporabljajo te izdelke, o tem varnostnem obvestilu in potrdite, da prizadetih izdelkov več ne uporabljate.
Please inform all employees who use the products about this Field Safety Notice and confirm that you are not using the affected products.

Podpisani potrjuje (prosimo, ustrezno označite)
The undersigned confirms (please tick as appropriate)

- [x] da ne bo uporabljal prizadetih izdelkov / *that he will not use the affected products,*
- [x] da je o tej pomembni informaciji obvestil vse uporabnike oz. vpletene osebe
that he has informed all persons involved about this important information,
- [] da omenjenih izdelkov ne poseduje več
that he no longer possesses the mentioned products,
- [] da omenjenih izdelkov ni prodal tretjim osebam
that he has not sold the mentioned products to third parties,
- [x] da je obvestil tretje osebe, če so od njega prejele omenjene izdelke o tem varnostnem obvestilu in o neuporabi teh izdelkov.
that he has informed third parties, if they have received the mentioned products from him, of the Field Safety Notice and non-use of the products.

