RAN-Formular (Rapid-Alert-Notification) zur Mitteilung über den RAS-Verteiler

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Medicinal Product Falsification

☒ **ASSUMED** ☐ **REASONABLY SUSPECTED** ☐ **VERIFIED**

Regierungspräsidium Karlsruhe
Referat 25 – Ärztliche und Pharmazeutische Angelegenheiten
Markgrafenstr. 46
76133 Karlsruhe

1. To / Empfänger:		FAX
☒	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-4636
☐	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	030-18444-30409
☐	Paul-Ehrlich-Institut / Bundesamt für Sera und Impfstoffe - (PEI)	06103-77-1263
☒	Ministerium für Soziales und Integration Baden-Württemberg, Referat 53, Else-Josenhans-Str. 6, 70173 Stuttgart	0711-123-3816

2. *Classification (not mandatory)*	3. Falsification
4. Product: Cockfosters ™ 100	5. Marketing Authorisation Number: * GUJ/DRUGS-G/25/1325 For use in humans/ (delete as required)
6. Brand/Trade Name: Cockfosters ™ 100	7. INN or Generic Name:
8. Dosage Form: Tablets	9. Strength: 100 mg Sildenfafil
10. Batch number (and bulk, if different): TC-080001	11. Expiry Date: 02/2022
12. Pack size and Presentation: 10X10 tablets	13. Date Manufactured: 03/20219
14. Marketing Authorisation Holder: * Shree Venkatesh (India)	
15. Manufacturer†: Contact Person: Telephone:	16. Recalling Firm

17. Rapid Alert Notification Reference Number: **DE_**		
18. Details:		
19. Information on distribution including exports (e.g. type of customer, e.g. hospitals): * Suspicion of the distribution of drugs through illegal distribution channels DB Consult s.r.o Klincova 35 82108 Bratislava 3 Slovakia		
20. Action taken by Issuing Authority: FOR YOUR INFORMATION The goods were secured by the customs office		
21. Proposed Action:		
22. From (Issuing Authority): Regierungspräsidium Karlsruhe mail to: abteilung2@rpk.bwl.de	23. Contact Person: Sabine Hofsäss Telephone: +49 721 926 7641	
24. Signed: Sabine Hofsäss	25. Date: 14.05.2021	26. Time: *

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has certified the batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.