


**IMPORTANT – DELIVER IMMEDIATELY**
Rapid Alert Notification of a Quality Defect / Recall

		Reference Number PT/DGAV/QD/RAS/2022/01/II.
Direção Geral de Alimentação e Veterinária Campo Grande, 50. 1700-093 Lisboa - Portugal		
1. To: All Competent Authorities.		
2. Product Recall Class of Defect: I II III (circle one)		3. Falsification / Fraud (specify)* No.
4. Product: Salmovac 440 Liofilizado para administração na água de bebida.	5. Marketing Authorisation Number:* R725/03 DGV. For use in animals.	
6. Brand/Trade Name: Salmovac 440 Liofilizado para administração na água de bebida.	7. INN or Generic Name: Salmonella enteritidis, mutant, strain 441/014.	
8. Dosage Form: Lyophilisate for use in drinking water.	9. Strength: -	
10. Batch number (and bulk, if different): 3320321.	11. Expiry Date: 26/11/2022.	
12. Pack size and Presentation: -	13. Date Manufactured: * 03/12/2021.	
14. Marketing Authorisation Holder: * Ceva Saúde Animal - Produtos Farmacêuticos e Imunológicos, Lda. Contact Person: Amélia Pimentel Telephone: (+351) 938 553 240.		
15. Manufacturer: IDT Biologika GmbH. Am Pharmapark 06861 Dessau-Rosslau Germany. Contact Person: Dr. Uta Schurig Telephone: +49 34901 885-4507.	16. Recalling Firm (if different): Ceva Saúde Animal - Produtos Farmacêuticos e Imunológicos, Lda. Contact Person: Amélia Pimentel Telephone: +351 938 553 240.	
17. Recall Number Assigned (if available): PT/DGAV/DQ/2022/01/II.		
18. Details of Defect/Reason for Recall: Information from PEI, on confirmed Out-Of-Specification result for the number of colony forming units at 10 months stability tests of batch 3320321 (exp. 26/11/2022) of Salmovac SE/440.		
19. Information on distribution including exports (type of customer, e.g. hospitals): * The packages had been distributed to wholesalers, veterinarians and final consumers (Animal owners). The batch had been distributed to Bulgaria, Greece, Italy, Portugal, Romania, Slovakia, Serbia, Spain and UK.		
20. Action taken by Issuing Authority: The recall had been initiated voluntarily by MAH until final consumers (Animal owners). All actions will be notified by MAH and monitored by DGAV.		
21. Proposed Action: Recall of above-mentioned batch.		

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Держпродспоживслужба
№11.1.1-5/4882 від 09.05.2022
КЕП: ШЕВЧЕНКО О. П. 09.05.2022 15:46
2B6C7DF9A3891DA1040000005C9DAA00EA041A03

22. From (Issuing Authority): Direção Geral de Alimentação e Veterinária		23. Contact Person: Henrique Ramos da Costa Telephone: + 351 217 808 221 Fax: + 351 217 808 251
24. Signed: 	25. Date: 2022-04-29.	26. Time: * 17:30 UTC.

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 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.

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