Rev 1: September 2018

FSN Ref: Non-conformity No.:285-2020

Date: 11.12.2020

Urgent Field Safety Notice
3459 Pneumococcus CWPS, 10 mg,

Error on label on Product no (REF): 3459 Pneumococcus CWPS, 10 mg, Lot. ZCWPS1-1, expire date 2024.01.09.

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

Field Safety Notice (FSN)

Error on label on Product no (REF): 3459 Pneumococcus CWPS, 10 mg, Lot. ZCWPS1-1, expire date. 2024.01.09.

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Antigen Product: Pneumococcus CWPS (Cell Wall PolySaccharide)
1.	2. Commercial name(s)
	Pneumococcus CWPS, 10 mg,
1.	3. Unique Device Identifier(s) (UDI-DI)
	GTIN13: 5713106034590 GMDN: 64703
1.	4. Primary clinical purpose of device(s)*
	The intended use is CWPS and CWPS Multi are intended for preabsorbing human serum samples before quantitation of specific pneumococcal capsular polysaccharide antibodies. CWPS and CWPS Multi may also be used as a coating agent during performance of an ELISA test.
1.	5. Device Model/Catalogue/part number(s)*
	REF: 3459
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	ZCWPS1-1
1.	8. Associated devices
	N/A

2 **Reason for Field Safety Notice**	
2.	1. Description of the product problem*
	On the correct label the following is printed: Pneumococcus CWPS, 10 mg, REF: 3459, Lot: ZCWPS1-1, expire date: 2024.01.09 Product number (REF) is wrong (differs from REF: 3459) on some labels. Lot number ZCWPS1-1 and expire date is correct.
2.	2. Hazard giving rise to the FSCA*
	Minor hazard as the product is not affected.
2.	3. Probability of problem arising
	Wrong use of product since the user believe it is a different product
2.	4. Predicted risk to patient/users
	No risk to patients/users
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Label Printer error, in a way that the product number (REF) is wrong on some labels of this lot. Lot number and expire date is correct.
2.	7. Other information relevant to FSCA
	No FSCA have been issue, this FSN is for information only

	3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User* ☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None	
3.	2. By when should the action be completed?	As soon as possible and latest 15. February 2021
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? N/A	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	2021-02-15
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	N/A	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	No follow up necessary
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	SSI Diagnostica A/S
	b. Address	Herredsvejen 2, 3400 Hillerød, Denmark
	c. Website address	www.ssidiagnostica.com
4.	8. The Competent (Regulatory) Authority of your country is been informed about this communication to customers.	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature 2020-12-14	**.....** **.....** **.....**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Customer Acknowledgment form

Please read this document in conjunction with Field Safety Notice 3459 Pneumococcus CWPS, 10 mg and return the completed and signed form as soon as possible but no later than 2021.02.15 to SSI Diagnostica A/S
By completing the form, you confirm you have destroyed, returned and/or used all vials of the lot covered by the FSN.

Name of Site	
Name of organization covered by this response	
Email address	
Telephone Number	
Name	
Signature	
Date	