Rev 1: September 2018

FSN Ref: **EU FSN 1/30/2024**

FSCA Ref: Manufacturer's ref number
EU FSCA 1/30/2024

Date: 01/30/2024

Urgent Field Safety Notice
Device Commercial Name

For Attention of*:Healthcare professionals

Contact details of local representative (name, e-mail, telephone, address etc.)*
Contract Person: Linda Moore, Email: lmoore@itldental.com, Tel: +14085040565

Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	ITL Dental Implant System Devices
1.	2. Commercial name(s)
	NA
1.	3. Unique Device Identifier(s) (UDI-DI)
	NA
1.	4. Primary clinical purpose of device(s)*
	Dental implantation
1.	5. Device Model/Catalogue/part number(s)*
	NA
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	The customer has to verify the label if it has CE Mark symbol and the NB 2862, in that case the customer has to return back the product to the distributor or destroy it. In both cases, the customer can ask for replacement or refund.
1.	8. Associated devices
	NA

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	During a MDSAP/EU MDR 2017/745 audit a template with the CE mark was put on 7 devices to be shipped – it was discovered, and the labels changed. Even though ITL Dental does not ship directly to the EU, the auditor thought that there still could be a possibility that Class IIa/b devices were shipped mislabelled with the CE Mark with notified body #2862 and Class I devices with the CE mark and #2862. There is no harm to patients or end users.
2.	2. Hazard giving rise to the FSCA*
	The patient might have used a non-compliant product.
2.	3. Probability of problem arising
	The probability is very low
2.	4. Predicted risk to patient/users
	There is no risk to patients or clinicians as this was a mislabelling of the CE mark and contained within the manufacturing site.
2.	5. Further information to help characterise the problem
	NA
2.	6. Background on Issue
	The mislabelling of the devices happened in ITL Dental's office in Irvine, CA, USA which were not shipped into the EU but the Notified Body requested that we notify potential users that the CE mark was misplaced and a new label will be sent if needed
2.	7. Other information relevant to FSCA
	NA

	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?	Specify where critical to patient/end user safety By March 31th , 2024
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No The Legal manufacturer have not shipped the product to EU , the FSN is intened to communicate the issue to potential impacted customers. The legal manufacturer is taking an action to verify if the non-eu distributors have shipped the non-compliant product to EU.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes email sales@itldental.com
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None **The customer has to reply only if they have a label with NB # 2862**	
3	6. By when should the action be completed?	March 31th , 2024
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? Not appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	NA
4.	3. For Updated FSN, key new information as follows:	
	NA	
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:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	
	b. Address	
	c. Website address	
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	

	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..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.