

RECALL OF A MEDICAL DEVICE

___ MM-JJ

Name

Address

Dear Ladies and Gentlemen,

We would like to inform you that Ivoclar Vivadent AG recalls the product IPS e.max ZirCAD CER/inLab LT C17 as a precautionary measure.

Reason: Restoration made of IPS e.max ZirCAD LT C17 showed cracks after sintering.

Risk assessment: In general, the defective restoration can be recognized directly after sintering. In the case of inserting the restoration into the patient's mouth, the restoration can fracture and can easily be replaced by a new restoration.

- Please check your storage facility and block the stock of the respective products / batches.
- Please contact the author of this letter by E-mail and inform him/her about the quantity of the product blocked in your storage facility.
- Below, we will inform you about the quantities of the products in question delivered to you:

Art. No.	Description	Batch No.	Delivered quantity	Delivery date

The batch number (lot number) can be found on the product and/or the respective packaging.



Please take the following measures:

- Stop deliveries of the batches/products in question
- Inventory of the batches/products in question
Please let us know by E-mail, the individual quantities of the batches/products in question.
Contact person: **name / e.mail address**
- Please return all your stocks of the batches/products in question to:
Company
Contact person
Address

You will receive a corresponding credit note or replacement delivery immediately.

Measures taken by the company:

- A worn out tool for pressing of the blocks has been identified. The worn out tool has been replaced.
- Further corrective actions will be defined based on the findings of the Root Cause Analysis.

Additional information:

The manufacturer **Ivoclar Vivadent AG in Liechtenstein** is responsible for this recall and we confirm that the authorities have been informed accordingly. Should you have any further question, please contact the Ivoclar Vivadent Customer Services in your country. We would like to thank you in advance for your cooperation and understanding. We apologize for any inconvenience that may arise or may have arisen as a result of this matter.

Sincerely,

IVOCLAR VIVADENT AG

Name
Function

ANNEX – 03-2020-001-R/ IPS e.max ZirCAD LT C17 – cracks after sintering

Please return this completed form to the following address immediately:

Name
Address
E-mail
FAX

Customer	
Name:	
Contact person:	
Customer number:	Phone number:

Material - Tally			
Batch No.	Units received	Units blocked	Units delivered

Traceability			
Batch No.	Customer No. / Name	Delivered quantity	Date

Date:	
Name:	
Signature:	

Company stamp:	
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Document history / change history

Reason for the preparation / revision: New Creation (English translation of TEFO-01678-DE)

Replaces the following documents: none