ivoclar vivadent
passion vision innovation

WITHDRAWAL OF A MEDICAL DEVICE

__. June 2015

Name
Address line 1
Address line 2

Dear Ms / Dear Mr

This is to inform you of a voluntary market withdrawal. The products enlisted below all contain the component which has led to the defect. An examination of the defect calls for a restriction of the following article numbers/ charge numbers:

IPS e.max system

Product ID	Product name	Lot
609433AN	IPS e.max Ceram Glaze Spray 270 ml	U15124
597044	IPS e.max Ceram Glaze Powder 5 g	T43549
597042	IPS e.max Ceram Glaze Paste FLUO 3 g	U11702
597042	IPS e.max Ceram Glaze Paste FLUO 3 g	U16100
597042	IPS e.max Ceram Glaze Paste FLUO 3 g	U15900
597045	IPS e.max Ceram Glaze Powder FLUO 5 g	U01576
597042	IPS e.max Ceram Glaze Paste FLUO 3 g	U01578
597042	IPS e.max Ceram Glaze Paste FLUO 3 g	U09829
597045	IPS e.max Ceram Glaze Powder FLUO 5 g	U20320
597041	IPS e.max Ceram Glaze Paste 3 g	T43527
634606	IPS e.max CAD Crystall./Connect 6.5g 1	U09241
634611	IPS e.max CAD Crystall./Connect 6.5g 6	U18858
634609	IPS e.max CAD Crystall./Connect 6.5g 4	U16908
596836AN	IPS e.max Ceram Essence Kit	U00065
596837AN	IPS e.max Ceram Shade Kit	U15536
591388PN	IPS e.max Ceram Basic Kit A-D	U19601
596828EN	IPS e.max Ceram Basic Kit	U15970
605474EN	IPS e.max Ceram Trial Kit (A2)	U21604
635528DN	IPS e.max CAD-on for inLab Basic Kit A-D	U19079
596836AN	IPS e.max Ceram Essence Kit	U11357
609432AN	IPS Empress Universal Glaze Spray 270 ml	U15124

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Konto CHF 324526-71 / BLZ 4835
IBAN: CH10 0483 5032 4526 7100 0

Rechtsform: Aktiengesellschaft
Sitz der Gesellschaft: 9494 Schaan
ÖR-Nr.: FL-0001.001.595-7
MWST-Nr. 50639

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The products can be identified as follows:
(Examples of the various dosage forms)

Product description	Product pictures
IPS e.max Ceram Glaze Spray	  U15124
IPS e.max Ceram Glaze Powder	  T43549
IPS e.max Ceram Glaze Powder fluo	  U01576 U20320
IPS e.max Ceram Glaze Paste fluo	  U11702 U16100 U15900 U01578 U09829
IPS e.max Ceram Glaze Paste	  T43527
IPS e.max CAD Crystall./Connect	  U09241 U18858 U16908 
IPS Empress Universal Glaze Spray	  U15124

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Reason for the voluntary withdrawal:

Despite careful examination and adherence to the regulatory standards, a defect has occured in the production process. The particles in the faulty component are larger than the size defined in the formula. On processing the concerned batches the user will not necessarily detect a fault. Attentive users however, will notice a more granular consistency or a different firing result after firing.

Health risk:

The respective charges fulfill the product-specific standard. The risks relating to patient safety were evaluated and marked as acceptable. There is no risk of a deterioration in the health status of the patients. Therefore the product recall will not include patients, but will be performed on a dealer level. No injuries or incidents have been reported yet.

Required measures:

- Cancellation of delivery of the respective charges/products
- Inventory of the concerned charges/products
  Please inform us per e-mail about the quantities of the concerned charges/products
  Contact person: Alexander Schwaszta (alexander.schwaszta@ivoclarvivadent.com)
- Please return all concerned product stocks that you have to:

  Ivoclar Vivadent AG
  Mr Alexander Schwaszta
  Bendererstr. 2
  FL-9494 Schaan
  Liechtenstein

You will be reimbursed with a credit voucher immediately.

Measures taken by the company:

Additional quality controls have been introduced in order to avoid a new occurence of this defect.

More informationen:

The manufacturer Ivoclar Vivadent AG in Liechtenstein is responsible for this voluntary withdrawal and we confirm that the authorities will be notified accordingly. If you have queries, please contact your local Ivoclar Vivadent customer sevice. We would like to thank you in advance for your cooperation and understanding and apologize for any inconveniences which have arisen or will arise.

Yours sincerely

IVOCLAR VIVADENT AG

Patrik Oehri
Director – Corporate Quality Management
Safety officer