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VITA Zahnfabrik H. Rauter GmbH & Co. KG

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Date: 16th March 2018

IMPORTANT SAFETY INFORMATION - VOLUNTARY RECALL

Background

An alle Handelspartner

A major component of VITA CEREC Powder (titanium dioxide) has been reclassified by the Committee for Risk Assessment following ECHA's risk assessment. Therefore we will not continue marketing this product any longer and also recall the products already in the market. This also applies to the accessory products VITA CEREC Propellant and VITA CEREC spray head for Propellant and CEREC Liquid. Categorization and classification of titanium dioxide have not yet been fully completed by dental experts. As a precautionary measure, VITA Zahnfabrik will withdraw these products from the market to eliminate even the slightest risk for patients and users.

Products concerned

The following product numbers are concerned:

VITA CEREC Powder
VITA CEREC Propellant
VITA CEREC spray head
VITA CEREC Liquid

(Prod. No. ECPO)
(Prod. No. ECS)
(Prod. No. ECS)
(Prod. No. ECL)

Products that are already in the market are not concerned.

Countermeasures

Please send the concerned products back to:

VITA Zahnfabrik H. Rauter GmbH & Co. KG Mr. Fredy Flum Ballyweg 6 79713 Bad Säckingen, Germany



Please enclose this letter with the shipment and inform us about the quantity of the returned products.

Product name	Quantity	Return of:
VITA CEREC Powder		- (customer's stamp)
(ProdNo. ECPO)		
VITA CEREC Propellant		
(Prod. No. ECPN)		
VITA CEREC spray head		
(Prod. No. ECS)		
VITA CEREC Liquid		
(Prod. No. ECL)		

Please make sure that all relevant persons in your organization are aware of this safety information. Please also forward this information to organizations that are affiliated with your company and are affected by these measures.

We would like to point out that the competent national authorities have been informed about this corrective measure.

If you have any questions concerning this information, feel free to contact us:

Contact	Telephone	Email
Bernd Walker (Head of QM & RA)	07761 562 361	b.walker@vita-zahnfabrik.de
Jens Bagemihl (Head of Sales Marketing)	07761 562 305	j.bagemihl@vita-zahnfabrik.com

VITA Zahnfabrik is committed to providing you with high-quality products at all times and apologizes for any inconvenience you may experience in connection with this safety measure.

VITA CEREC Powder as well as the relevant accessory products can be substituted without any problems by:

VITA Powder Scan Spray (Art.-Nr. ECSCAN75V1)

Best Regards

VITA Zahnfabrik H. Rauter GmbH & Co. KG

Bernd Walker Head of QM & RA

Bernd Schnakenberg Head of Sales & Marketing