

---

VITA Zahnfabrik H. Rauter GmbH & Co. KG · P.O. Box 1338 · D-79704 Bad Säckingen, Germany

VITA Zahnfabrik  
H. Rauter GmbH & Co. KG  
Postfach 13 38  
D-79704 Bad Säckingen, Germany

Telefon: +49 (0)77 61-562-0  
Telefax: +49 (0)77 61-562-299

An alle Handelspartner

Date: 16th March 2018

---

## IMPORTANT SAFETY INFORMATION - VOLUNTARY RECALL

### **Background**

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	<b>(Prod. No. ECPO)</b>
VITA CEREC Propellant	<b>(Prod. No. ECPN)</b>
VITA CEREC spray head	<b>(Prod. No. ECS)</b>
VITA CEREC Liquid	<b>(Prod. No. ECL)</b>

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 (Prod.-No. ECPO)		(customer's stamp)
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