



EU-Konformitätserklärung *EU Declaration of conformity*

Hersteller/ *Manufacturer:*

VITA Zahnfabrik H. Rauter GmbH & Co. KG
Spitalgasse 3, 79713 Bad Säckingen, Germany

Produkt/ *Product:*

VITA ENAMIC®

Basis-UDI-DI /
Basic UDI-DI:

++J017CC0PU

Gemeinsame Spezifikation /
Common specification:

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SRN:

DE-MF-000005906

Klassifizierung / Regel /
Classification / Rule:

Ila / Regel 8 (gemäß Anhang 8)
Ila / Rule 8 (according to Annex 8)

Zweckbestimmung /
Intended purpose:

VITA ENAMIC Produkte sind keramische Materialien für
dentale Behandlungen.

*VITA ENAMIC products are ceramic materials for dental
treatments.*

Zertifikat / *Certificate:*

50069-60-03-00

Benannte Stelle /
Notified body:

DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart, Germany
(Kennnummer / *Identification number* 0124)

Konformitätsbewertungs-
verfahren /
*Conformity assessment
procedure:*

Anhang IX, Kapitel I und III der Verordnung (EU) 2017/745
Annex IX, Chapter I and III of Regulation (EU) 2017/745

Hiermit erklären wir in alleiniger Verantwortung, dass sich das oben genannte Medizinprodukt
im Einklang mit der Verordnung (EU) 2017/745 befindet.

*We hereby declare under our sole responsibility that the above-mentioned medical device is in
compliance with the Regulation (EU) 745/2017.*

Bad Säckingen, 12.10.2026

Müller, Sindy
Person Responsible for Regulatory
Compliance (PRRC)



Déclaration de conformité UE

Dichiarazione di conformità UE

Fabricant / *Fabbricante*:**VITA Zahnfabrik H. Rauter GmbH & Co. KG**
Spitalgasse 3, 79713 Bad Säckingen, GermanyProduit / *Prodotto*:**VITA ENAMIC®**

IUD-ID de base /

++J017CC0PU

UDI-DI di base:

Spécifications communes /

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Specifiche comuni:

SRN:

DE-MF-000005906

Classification / Règle /

IIa / Règle 8 (conformément à Annexe 8)

*Classificazione / Regola:**IIa / Regola 8 (secondo Allegato 8)*

Destination /

Les produits VITA ENAMIC sont des matériaux céramique
pour traitements dentaires.*Destinazione d'uso:**I prodotti VITA ENAMIC sono materiali ceramici per trattamenti
dentali.*Certificats / *Certificato*:

50069-60-03-00

Organisme notifié /

DEKRA Certification GmbH

*Organismo notificato:*Handwerkstraße 15, 70565 Stuttgart, Germany
(Numéro d'identification / *numero di identificazione* 0124)Procédure d'évaluation de la
conformité /Annexe IX, Chapitre I et III du Règlement (UE) 2017/745
*Allegato IX, Capo I e III della Regolamento (UE) 2017/745**Procedura di valutazione
della conformità:*

Nous déclarons par la présente, sous notre seule responsabilité, que le dispositif médical
susmentionné est conforme à l'annexe I du règlement UE 745/2017.

*Con la presente dichiariamo sotto la nostra esclusiva responsabilità che il suddetto dispositivo
medico è conforme all'allegato I del regolamento UE 745/2017.*

Bad Säckingen, 12.10.2026

Müller, Sindy

Person Responsible for Regulatory
Compliance (PRRC)



Declaración UE de conformidad *Declaração UE de conformidade*

Fabricante / *Fabricante:*

VITA Zahnfabrik H. Rauter GmbH & Co. KG
Spitalgasse 3, 79713 Bad Säckingen, Germany

Product / *Produto:*

VITA ENAMIC®

UDI-DI básico /
UDI-DI básico:

++J017CC0PU

Especificaciones comunes /
Especificações comuns:

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SRN:

DE-MF-000005906

Clasificación / Regla /
Classificação / Regra:

Ila / Regla 8 (según Anexo 8)
Ila / Regra 8 (segundo Anexo 8)

Finalidad prevista /
Finalidade prevista:

Los productos VITA ENAMIC son materiales cerámicos para
tratamientos dentales.

*Os produtos VITA ENAMIC são materiais cerâmicos para
tratamentos dentários.*

Certificado / *Certificado:*

50069-60-03-00

Organismo notificado /
Organismo notificado:

DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart, Germany
(número de identificación / *número de identificação* 0124)

Procedimiento de evaluación
de la conformidad /
*Procedimento de avaliação
da conformidade:*

Anexo IX, Capítulo I y III de Reglamento (UE) 2017/745
Anexo IX, Capítulo I e III do Regulamento (UE) 2017/745

Por la presente declaramos, bajo nuestra exclusiva responsabilidad, que el producto sanitario
arriba mencionado cumple con el anexo I del Reglamento UE 745/2017.

*Declaramos sob a nossa exclusiva responsabilidade que o dispositivo médico acima
mencionado está em conformidade com o Anexo I do Regulamento da UE 745/2017.*

Bad Säckingen, 12.10.2026

Müller, Sindy
Person Responsible for Regulatory
Compliance (PRRC)



EU-izjava o skladnosti *ES atbilstības deklarācija*

Proizvajalec / Ražotājs:

VITA Zahnfabrik H. Rauter GmbH & Co. KG
Spitalgasse 3, 79713 Bad Säckingen, Germany

Izdelek / Produkts:

VITA ENAMIC®Osnovni UDI-DI /
Pamata UDI-DI:

++J017CC0PU

Skupna specifikacija /
Kopīgā specifikācija:

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SRN:

DE-MF-000005906

Klasifikacija / pravilo /
Klasifikācija / Noteikums:IIa / Pravilo 8 (v skladu s Prilogo 8)
IIa / 8. noteikums (saskaņā ar 8. pielikumu)Namen /
Paredzētais lietojums:Izdelki VITA ENAMIC so keramični materiali za dentalne
obravnavas.*VITA ENAMIC produkti ir keramikas materiāli izmantošanai
zobārstniecībā.*

Certifikat / Sertifikāts:

50069-60-03-00

Priglašeni organ /
Pilnvarotā iestāde:DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart, Germany
(Karakteristiska številka / identifikācijas numurs 0124)Postopek ocenjevanja
skladnosti /
Atbilstības novērtēšanas
procedūra:Priloga IX, poglavji I in III Uredbe (EU) 2017/745 Annex IX
Anexo IX, Capítulo I y III de Reglamento (UE) 2017/745
Regulas (ES) 2017/745 IX pielikums, I un III nodaļa

Na lastno odgovornost izjavljamo, da je zgoraj naveden medicinski pripomoček v skladu z
Uredbo (EU) 2017/745.

*Uzņemoties pilnu atbildību, ar šo mēs apliecinām, ka iepriekš minētā medicīniskā ierīce atbilst
Regulai (ES) 2017/745.*

Bad Säckingen, 12.10.2026

Müller, Sindy
Person Responsible for Regulatory
Compliance (PRRC)



AB Uygunluk Beyanı

Üretici

VITA Zahnfabrik H. Rauter GmbH & Co. KG
Spitalgasse 3, 79713 Bad Säckingen, Germany

Ürün / Product:

VITA ENAMIC®

Temel -UDI-DI

++J017CC0PU

Ortak Spesifikasyon

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SRN:

DE-MF-000005906

Sınıflandırma / Kural:

Ila / Kural 8 (Ek 8'e göre)

Kullanım amacı:

VITA ENAMIC Ürünleri, diş tedavisi için kullanılan seramik materyallerdir.

Sertifika:

50069-60-03-00

Onaylanmış kuruluş:

DEKRA Certification GmbH
Handwerkstraße 15, 70565 Stuttgart, Germany
(Kimlik numarası 0124)

Uygunluk değerlendirme
prosedürü:

2017/745 (AB) sayılı Yönetmelik, Ek IX, Bölüm I ve III

Yegâne sorumluluğumuzda, yukarıda belirtilen tıbbi cihazın 745/2017 (AB) sayılı Yönetmeliğe uygun olduğunu beyan ederiz.

Bad Säckingen, 12.10.2026

Müller, Sindy
Person Responsible for Regulatory
Compliance (PRRC)

**Anhang I zur EU-Konformitätserklärung
Annex I to EU Declaration of conformity
Annexe I de la Déclaration de conformité UE
Allegato I della Dichiarazione di conformità UE
Anexo I de la Declaración UE de conformidad
Anexo I da Declaração UE de conformidade
Priloga I k EU-izjavi o skladnosti
ES atbilstības deklarācijas I pielikums
AB Uygunluk Beyanı, Ek I**

VITA ENAMIC®

Artikelnr. / Item No. / Cod art. / Num d'article / N.º art. / N.º de artigo / Št. Artikla / Artikula nr. / Madde No.	Beschreibung / Description / Descrizione / Description / Descripción / Descrição / Opis / Apraksts / Açıklama
EC40M1HTEM14	VITA ENAMIC for CEREC/inLab, 0M1-HT, EM-14, 5 pcs.
EC41M1HTEM14	VITA ENAMIC for CEREC/inLab, 1M1-HT, EM-14, 5 pcs.
EC41M2HTEM14	VITA ENAMIC for CEREC/inLab, 1M2-HT, EM-14, 5 pcs.
EC42M2HTEM14	VITA ENAMIC for CEREC/inLab, 2M2-HT, EM-14, 5 pcs.
EC43M2HTEM14	VITA ENAMIC for CEREC/inLab, 3M2-HT, EM-14, 5 pcs.
EC40M1HTEM10	VITA ENAMIC for CEREC/inLab, 0M1-HT, EM-10, 5 pcs.
EC41M1HTEM10	VITA ENAMIC for CEREC/inLab, 1M1-HT, EM-10, 5 pcs.
EC41M2HTEM10	VITA ENAMIC for CEREC/inLab, 1M2-HT, EM-10, 5 pcs.
EC42M2HTEM10	VITA ENAMIC for CEREC/inLab, 2M2-HT, EM-10, 5 pcs.
EC43M2HTEM10	VITA ENAMIC for CEREC/inLab, 3M2-HT, EM-10, 5 pcs.
EC4EM4282765	VITA ENAMIC for CEREC/inLab, 4M2-HT, EM-14, 5 pcs.
EC4EM4282645	VITA ENAMIC for CEREC/inLab, 4M2-HT, EM-10, 5 pcs.
EC40M1TEM14	VITA ENAMIC for CEREC/inLab, 0M1-T, EM-14, 5 pcs.
EC41M1TEM14	VITA ENAMIC for CEREC/inLab, 1M1-T, EM-14, 5 pcs.
EC41M2TEM14	VITA ENAMIC for CEREC/inLab, 1M2-T, EM-14, 5 pcs.
EC42M2TEM14	VITA ENAMIC for CEREC/inLab, 2M2-T, EM-14, 5 pcs.
EC43M2TEM14	VITA ENAMIC for CEREC/inLab, 3M2-T, EM-14, 5 pcs.
EC4EM3282765	VITA ENAMIC for CEREC/inLab, 4M2-T, EM-14, 5 pcs.
EC4EM4112645	VITA ENAMIC for CEREC/inLab, 2M1-HT, EM-10, 5 pcs.
EC4EM4132645	VITA ENAMIC for CEREC/inLab, 2M3-HT, EM-10, 5 pcs.
EC4EM4192645	VITA ENAMIC for CEREC/inLab, 3M1-HT, EM-10, 5 pcs.
EC4EM4212645	VITA ENAMIC for CEREC/inLab, 3M3-HT, EM-10, 5 pcs.
EC4EM4112765	VITA ENAMIC for CEREC/inLab, 2M1-HT, EM-14, 5 pcs.
EC4EM4132765	VITA ENAMIC for CEREC/inLab, 2M3-HT, EM-14, 5 pcs.
EC4EM4192765	VITA ENAMIC for CEREC/inLab, 3M1-HT, EM-14, 5 pcs.
EC4EM4212765	VITA ENAMIC for CEREC/inLab, 3M3-HT, EM-14, 5 pcs.
EC4EM3112765	VITA ENAMIC for CEREC/inLab, 2M1-T, EM-14, 5 pcs.
EC4EM3132765	VITA ENAMIC for CEREC/inLab, 2M3-T, EM-14, 5 pcs.
EC4EM3192765	VITA ENAMIC for CEREC/inLab, 3M1-T, EM-14, 5 pcs.

EC4EM3212765	VITA ENAMIC for CEREC/inLab, 3M3-T, EM-14, 5 pcs.
EC4EM7062765	VITA ENAMIC for CEREC/inLab, 1M1-ST, EM-14, 5 pcs.
EC4EM7072765	VITA ENAMIC for CEREC/inLab, 1M2-ST, EM-14, 5 pcs.
EC4EM7122765	VITA ENAMIC for CEREC/inLab, 2M2-ST, EM-14, 5 pcs.
EC4EM7202765	VITA ENAMIC for CEREC/inLab, 3M2-ST, EM-14, 5 pcs.
EC4EM7282765	VITA ENAMIC for CEREC/inLab, 4M2-ST, EM-14, 5 pcs.
EN1EM4022765	VITA ENAMIC UNIVERSAL; 0M1-HT, EM-14, 5 pcs.
EN1EM4062765	VITA ENAMIC UNIVERSAL; 1M1-HT, EM-14, 5 pcs.
EN1EM4072765	VITA ENAMIC UNIVERSAL; 1M2-HT, EM-14, 5 pcs.
EN1EM4122765	VITA ENAMIC UNIVERSAL; 2M2-HT, EM-14, 5 pcs.
EN1EM4202765	VITA ENAMIC UNIVERSAL; 3M2-HT, EM-14, 5 pcs.
EN1EM4282765	VITA ENAMIC UNIVERSAL; 4M2-HT, EM-14, 5 pcs.
EN1EM4022645	VITA ENAMIC UNIVERSAL; 0M1-HT, EM-10, 5 pcs.
EN1EM4062645	VITA ENAMIC UNIVERSAL; 1M1-HT, EM-10, 5 pcs.
EN1EM4072645	VITA ENAMIC UNIVERSAL; 1M2-HT, EM-10, 5 pcs.
EN1EM4122645	VITA ENAMIC UNIVERSAL; 2M2-HT, EM-10, 5 pcs.
EN1EM4202645	VITA ENAMIC UNIVERSAL; 3M2-HT, EM-10, 5 pcs.
EN1EM4282645	VITA ENAMIC UNIVERSAL; 4M2-HT, EM-10, 5 pcs.
EN1EM3022765	VITA ENAMIC UNIVERSAL; 0M1-T, EM-14, 5 pcs.
EN1EM3062765	VITA ENAMIC UNIVERSAL; 1M1-T, EM-14, 5 pcs.
EN1EM3072765	VITA ENAMIC UNIVERSAL; 1M2-T, EM-14, 5 pcs.
EN1EM3122765	VITA ENAMIC UNIVERSAL; 2M2-T, EM-14, 5 pcs.
EN1EM3202765	VITA ENAMIC UNIVERSAL; 3M2-T, EM-14, 5 pcs.
EN1EM3282765	VITA ENAMIC UNIVERSAL; 4M2-T, EM-14, 5 pc
EN1EM7062765	VITA ENAMIC UNIVERSAL; 1M1-ST, EM-14, 5 pcs.
EN1EM7072765	VITA ENAMIC UNIVERSAL; 1M2-ST, EM-14, 5 pcs.
EN1EM7122765	VITA ENAMIC UNIVERSAL; 2M2-ST, EM-14, 5 pcs.
EN1EM7202765	VITA ENAMIC UNIVERSAL; 3M2-ST, EM-14, 5 pcs.
EN1EM7282765	VITA ENAMIC UNIVERSAL; 4M2-ST, EM-14, 5 pcs.
EPMEM4022765	VITA ENAMIC for PlanMill, 0M1-HT, EM-14, 5 pcs.
EPMEM4062765	VITA ENAMIC for PlanMill, 1M1-HT, EM-14, 5 pcs.
EPMEM4072765	VITA ENAMIC for PlanMill, 1M2-HT, EM-14, 5 pcs.
EPMEM4122765	VITA ENAMIC for PlanMill, 2M2-HT, EM-14, 5 pcs.
EPMEM4202765	VITA ENAMIC for PlanMill, 3M2-HT, EM-14, 5 pcs.
EPMEM4282765	VITA ENAMIC for PlanMill, 4M2-HT, EM-14, 5 pcs.
EPMEM3022765	VITA ENAMIC for PlanMill, 0M1-T, EM-14, 5 pcs.
EPMEM3062765	VITA ENAMIC for PlanMill, 1M1-T, EM-14, 5 pcs.
EPMEM3072765	VITA ENAMIC for PlanMill, 1M2-T, EM-14, 5 pcs.
EPMEM3122765	VITA ENAMIC for PlanMill, 2M2-T, EM-14, 5 pcs.
EPMEM3202765	VITA ENAMIC for PlanMill, 3M2-T, EM-14, 5 pcs.
EPMEM3282765	VITA ENAMIC for PlanMill, 4M2-T, EM-14, 5 pcs.
EC4EC4062765	VITA ENAMIC multiColor for CEREC/inLab, 1M1-HT, EMC-14, 5 pcs.
EC4EC4072765	VITA ENAMIC multiColor for CEREC/inLab, 1M2-HT, EMC-14, 5 pcs.
EC4EC4122765	VITA ENAMIC multiColor for CEREC/inLab, 2M2-HT, EMC-14, 5 pcs.
EC4EC4202765	VITA ENAMIC multiColor for CEREC/inLab, 3M2-HT, EMC-14, 5 pcs.
EC4EC4282765	VITA ENAMIC multiColor for CEREC/inLab, 4M2-HT, EMC-14, 5 pcs.
EC4EC4062885	VITA ENAMIC multiColor for CEREC/inLab, 1M1-HT, EMC-16, 5 pcs.
EC4EC4072885	VITA ENAMIC multiColor for CEREC/inLab, 1M2-HT, EMC-16, 5 pcs.
EC4EC4122885	VITA ENAMIC multiColor for CEREC/inLab, 2M2-HT, EMC-16, 5 pcs.
EC4EC4202885	VITA ENAMIC multiColor for CEREC/inLab, 3M2-HT, EMC-16, 5 pcs.
EC4EC4282885	VITA ENAMIC multiColor for CEREC/inLab, 4M2-HT, EMC-16, 5 pcs.
EN1EC4062765	VITA ENAMIC multiColor UNIVERSAL, 1M1-HT, EMC-14, 5 pcs.
EN1EC4072765	VITA ENAMIC multiColor UNIVERSAL, 1M2-HT, EMC-14, 5 pcs.

EN1EC4122765	VITA ENAMIC multiColor UNIVERSAL, 2M2-HT, EMC-14, 5 pcs.
EN1EC4202765	VITA ENAMIC multiColor UNIVERSAL, 3M2-HT, EMC-14, 5 pcs.
EN1EC4282765	VITA ENAMIC multiColor UNIVERSAL, 4M2-HT, EMC-14, 5 pcs.
EN1EC4062885	VITA ENAMIC multiColor UNIVERSAL, 1M1-HT, EMC-16, 5 pcs.
EN1EC4072885	VITA ENAMIC multiColor UNIVERSAL, 1M2-HT, EMC-16, 5 pcs.
EN1EC4122885	VITA ENAMIC multiColor UNIVERSAL, 2M2-HT, EMC-16, 5 pcs.
EN1EC4202885	VITA ENAMIC multiColor UNIVERSAL, 3M2-HT, EMC-16, 5 pcs.
EN1EC4282885	VITA ENAMIC multiColor UNIVERSAL, 4M2-HT, EMC-16, 5 pcs.
EPMEC4062765	VITA ENAMIC multiColor for PlanMill, 1M1-HT, EMC-14, 5 pcs.
EPMEC4072765	VITA ENAMIC multiColor for PlanMill, 1M2-HT, EMC-14, 5 pcs.
EPMEC4122765	VITA ENAMIC multiColor for PlanMill, 2M2-HT, EMC-14, 5 pcs.
EPMEC4202765	VITA ENAMIC multiColor for PlanMill, 3M2-HT, EMC-14, 5 pcs.
EPMEC4282765	VITA ENAMIC multiColor for PlanMill, 4M2-HT, EMC-14, 5 pcs.
EC4EMC14HTSS	VITA ENAMIC® multiColor Sample Set HT
EC4HTEM14SS	VITA ENAMIC classical Sample Set A2, A3
ECOEC4062765	VITA ENAMIC multiColor for Core3d, 1M1-HT, EMC-14, 5 pcs.
ECOEC4072765	VITA ENAMIC multiColor for Core3d, 1M2-HT, EMC-14, 5 pcs.
ECOEC4122765	VITA ENAMIC multiColor for Core3d, 2M2-HT, EMC-14, 5 pcs.
ECOEC4202765	VITA ENAMIC multiColor for Core3d, 3M2-HT, EMC-14, 5 pcs.
ECOEC4282765	VITA ENAMIC multiColor for Core3d, 4M2-HT, EMC-14, 5 pcs.
EPMEC4062765P	VITA ENAMIC multiColor for PlanMill, 1M1-HT, EMC-14, 5 pcs.
EPMEC4072765P	VITA ENAMIC multiColor for PlanMill, 1M2-HT, EMC-14, 5 pcs.
EPMEC4122765P	VITA ENAMIC multiColor for PlanMill, 2M2-HT, EMC-14, 5 pcs.
EPMEC4202765P	VITA ENAMIC multiColor for PlanMill, 3M2-HT, EMC-14, 5 pcs.
EPMEC4282765P	VITA ENAMIC multiColor for PlanMill, 4M2-HT, EMC-14, 5 pcs.
EPMEM3022765P	VITA ENAMIC for PlanMill, 0M1-T, EM-14, 5 pcs.
EPMEM3062765P	VITA ENAMIC for PlanMill, 1M1-T, EM-14, 5 pcs.
EPMEM3072765P	VITA ENAMIC for PlanMill, 1M2-T, EM-14, 5 pcs.
EPMEM3122765P	VITA ENAMIC for PlanMill, 2M2-T, EM-14, 5 pcs.
EPMEM3202765P	VITA ENAMIC for PlanMill, 3M2-T, EM-14, 5 pcs.
EPMEM3282765P	VITA ENAMIC for PlanMill, 4M2-T, EM-14, 5 pcs.
EPMEM4062765P	VITA ENAMIC for PlanMill, 1M1-HT, EM-14, 5 pcs.
EPMEM4072765P	VITA ENAMIC for PlanMill, 1M2-HT, EM-14, 5 pcs.
EPMEM4122765P	VITA ENAMIC for PlanMill, 2M2-HT, EM-14, 5 pcs.
EPMEM4202765P	VITA ENAMIC for PlanMill, 3M2-HT, EM-14, 5 pcs.
EPMEM4022765P	VITA ENAMIC for PlanMill, 0M1-HT, EM-14, 5 pcs.
EPMEM4282765P	VITA ENAMIC for PlanMill, 4M2-HT, EM-14, 5 pcs.
EC4EM4362765	VITA ENAMIC A1-HT, EM-14, 5 pcs.
EC4EM4372765	VITA ENAMIC A2-HT, EM-14, 5 pcs.
EC4EM4382765	VITA ENAMIC A3-HT, EM-14, 5 pcs.
EC4EM4392765	VITA ENAMIC A3.5-HT, EM-14, 5 pcs.
EC4EM4402765	VITA ENAMIC A4-HT, EM-14, 5 pcs.
EC4EM4412765	VITA ENAMIC B1-HT, EM-14, 5 pcs.
EC4EM4452765	VITA ENAMIC C1-HT, EM-14, 5 pcs.