KONFORMITÄTSERKLÄRUNG / *DECLARATION OF CONFORMITY*

Name und Adresse der Firma / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Deutschland / *Germany* *SRN: DE-MF-000007705*

Wir erklären in alleiniger Verantwortung, dass / *We declare under our sole responsibility that*

das Medizinprodukt / *the medical device*	Paladur
Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl / *Name, type or model, batch or serial number, possibly sources and number of items*	Artikelliste siehe Anhang / *List of Articles see Annex*
EMDN-Nummer / *EMDN-Code* GMDN-Nummer / *GMDN code* UMDNS-Nummer / *UMDNS code* Basis-UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699mBC
der Klasse / *of class*	IIa
nach Regel / *according to rule*	5-3, 19-3 nach Anhang VIII der Medizinprodukte-Verordnung, 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

allen Anforderungen der Medizinprodukte-Verordnung 2017/745 entspricht, die anwendbar sind / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Zahnheilkunde – Kunststoffe – Teil 1: Prothesenkunststoffe / *Dentistry – Base polymers – Part 1: Denture base polymers* Weitere angewandte Normen siehe Version 04 der Technischen Dokumentation von Product Paladur / *Further Applied standards see Technical Documentation of Product Paladur, Version 04*
Konformitätsbewertungsverfahren nach / *Conformity assessment procedure acc. to*	Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I, Abschnitt 2 und 3 und Kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Benannte Stelle / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Germany CE 0197
Registrierungsnr. / *Registration No.:*	HZ 1198082-1
Versionsnummer / *Version number*	03
Ersetzt Konformitätserklärung vom / *Replaces Declaration of Conformity from*	04.01.2023
Hanau, 02.01.2025 Ort, Datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Name und Funktion / *Name and function*

Diese Konformitätserklärung ist gültig für 2 Jahre in Verbindung mit den Freigabe-Dokumenten für die jeweilige Charge der produzierten Medizinprodukte. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Artikelliste / *List of Articles*
Anhang zur Konformitätserklärung / Annex to declaration of conformity

das Medizinprodukt / *for the medical device*	Paladur
Versionsnummer Artikelliste/ *Version number article list*	02
Ersetzt Artikelliste vom / *Replaces article list from*	04.01.2023
Diese Artikelliste ist gültig für die Konformitätserklärung Version/ *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014647079370	64707937	Paladur, 80 ml DE/IT
+J014647079380	64707938	Paladur, 500 ml DE/GB/FR/NL
+J014647079450	64707945	Paladur, rosa, 100 g
+J014647079480	64707948	Paladur, farblos, 100 g
+J014647079540	64707954	Paladur, rosa, 500 g
+J014647079560	64707956	Paladur, 500 g, rosa geadert
+J014647079570	64707957	Paladur, farblos, 500 g
+J014647079630	64707963	Paladur, rosa, 1000 g
+J014647079650	64707965	Paladur, rosa geadert, 1000 g
+J014647079660	64707966	Paladur, farblos, 1000 g
+J014647079670	64707967	Paladur, R 50 geadert, 1000 g
+J014660707260	66070726	Paladur, 500ml IT/ES/DK/GR/SK

Hanau, 02.01.2025

Ort, Datum / *Place, date*

i.V.
Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Name und Funktion / *Name and function*

OVERENSSTEMMELSESERKLÆRING / *DECLARATION OF CONFORMITY*

Virksomhedens navn og adresse / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, D-63450 Hanau Tyskland / *Germany* *SRN: DE-MF-000007705*

Vi erklærer hermed på eget ansvar, at / *We declare under our sole responsibility that*

det medicinske udstyr / *the medical device*	Paladur
Betegnelse, type eller model, batch- eller serienummer samt eventuelt oprindelse og antal emner / *Name, type or model, batch or serial number, possibly sources and number of items*	Produktlisten kan ses i bilaget / *List of Articles see Annex*
EMDN-kode / *EMDN-Code* GMDN-kode / *GMDN code* UMDNS-kode / *UMDNS code* Grundlæggende UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699mBC
i klasse / *of class*	IIa
i henhold til artikel / *according to rule*	5-3, 19-3 i bilag VIII i Europa-Parlamentets og Rådets forordning (EU) 2017/745 om medicinsk udstyr / *according to Annex VIII of Medical Device Regulation 2017/745*

lever op til alle de relevante bestemmelser i forordning (EU) 2017/745 om medicinsk udstyr. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Anvendte harmoniserede standarder, nationale standarder eller andre normative dokumenter / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Andre anvendte standarder kan ses i det tekniske dokumentationsmateriale til produktet Paladur, version 04 *Further Applied standards see Technical Documentation of Product Paladur, Version 04*
Overensstemmelsesvurderingsprocedure iht. / *Conformity assessment procedure acc. to*	Forordning (EU) 2017/745 om medicinsk udstyr, bilag IX, kapitel I, afsnit 2 og 3 samt kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Underrettet organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 D-90431 Nürnberg, Tyskland CE 0197
Registreringsnummer / *Registration number:*	HZ 1198082-1
Versionsnummer / *Version number*	03
Erstatter overensstemmelseserklæring fra / *Replaces Declaration of Conformity from*	04.01.2023
Hanau, 02.01.2025	på vegne af Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Sted, dato / *Place, date*	Navn og stilling / *Name and function*

Denne konformitetserkæring gælder i 2 år i forbindelse med frigivelsesdokumenterne for det aktuelle parti af produceret medicinsk udstyr. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Artikelliste / *List of Articles*
Bilag / *Annex*: Overensstemmelseserklæring / *Declaration of Conformity*

Det medicinske udstyr / *The medical device*	Paladur
Versionsnummer / *Version number*	02
Erstatter bilag fra / *Replaces Annex from*	04.01.2023
Denne artikelliste er gyldig i forbindelse med overensstemmelseserklæringen version / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Varenummer / *Article number***	**Betegnelse / *Name***
+J014647079370	64707937	Paladur, 80 ml DE/IT
+J014647079380	64707938	Paladur, 500 ml DE/GB/FR/NL
+J014647079450	64707945	Paladur, rosa, 100 g
+J014647079480	64707948	Paladur, farblos, 100 g
+J014647079540	64707954	Paladur, rosa, 500 g
+J014647079560	64707956	Paladur, 500 g, rosa geadert
+J014647079570	64707957	Paladur, farblos, 500 g
+J014647079630	64707963	Paladur, rosa, 1000 g
+J014647079650	64707965	Paladur, rosa geadert, 1000 g
+J014647079660	64707966	Paladur, farblos, 1000 g
+J014647079670	64707967	Paladur, R 50 geadert, 1000 g
+J014660707260	66070726	Paladur, 500ml IT/ES/DK/GR/SK

Hanau, 02.01.2025

Sted, dato / *Place, date*

i.V.

på vegne af Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Navn og stilling / *Name and function*

DECLARACIÓN DE CONFORMIDAD / *DECLARATION OF CONFORMITY*

Nombre y dirección de la empresa / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Alemania / *Germany* *SRN: DE-MF-000007705*

Declaramos bajo nuestra exclusiva responsabilidad que / *We declare under our sole responsibility that*

el producto sanitario / *the medical device*	Paladur
Nombre, tipo o modelo, lote o número de serie, posiblemente fuentes y número de elementos / *Name, type or model, batch or serial number, possibly sources and number of items*	Lista de artículos en el Anexo / *List of Articles see Annex*
Código EMDN / *EMDN-Code* Código GMDN / *GMDN code* Código UMDNS / *UMDNS code* UDI-DI básico / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699mBC
de la clase / *of class*	IIa
de acuerdo con la norma / *according to rule*	5-3, 19-3 de acuerdo con el Anexo VIII del Reglamento sobre productos sanitarios 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

cumple todas las disposiciones del Reglamento sobre productos sanitarios 2017/745 que se le aplican. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Normas armonizadas, normas nacionales u otros documentos normativos que se aplican / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Para otras normas aplicadas consulte la documentación técnica del producto Paladur, versión 04 *Further Applied standards see Technical Documentation of Product Paladur, Version 04*
Procedimiento de evaluación de la conformidad de acuerdo con / *Conformity assessment procedure acc. to*	Reglamento sobre productos sanitarios 2017/745 Anexo IX, Capítulo I, Secciones 2 y 3 y Capítulo III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organismo notificado / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Alemania CE 0197
Número de registro / *Registration number:*	HZ 1198082-1
Número de versión / *Version number*	03
Sustituye a la declaración de conformidad del / *Replaces Declaration of Conformity from*	04.01.2023

Hanau, 02.01.2025

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Lugar, fecha / *Place, date* — Nombre y cargo / *Name and function*

La presente declaración de conformidad tendrá una validez de 2 años según la documentación emitida para el correspondiente lote de productos fabricados. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Lista de artículos / *List of Articles*
Anexo / *Annex*: Declaración de conformidad / *Declaration of Conformity*

El producto sanitario / *The medical device*	Paladur
Número de versión / *Version number*	02
Sustituye al Anexo del / *Replaces Annex from*	04.01.2023
Esta lista de artículos es válida para la versión de la declaración de conformidad / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Número de artículo / *Article number***	**Nombre / *Name***
+J014647079370	64707937	Paladur, 80 ml DE/IT
+J014647079380	64707938	Paladur, 500 ml DE/GB/FR/NL
+J014647079450	64707945	Paladur, rosa, 100 g
+J014647079480	64707948	Paladur, farblos, 100 g
+J014647079540	64707954	Paladur, rosa, 500 g
+J014647079560	64707956	Paladur, 500 g, rosa geadert
+J014647079570	64707957	Paladur, farblos, 500 g
+J014647079630	64707963	Paladur, rosa, 1000 g
+J014647079650	64707965	Paladur, rosa geadert, 1000 g
+J014647079660	64707966	Paladur, farblos, 1000 g
+J014647079670	64707967	Paladur, R 50 geadert, 1000 g
+J014660707260	66070726	Paladur, 500ml IT/ES/DK/GR/SK

Hanau, 02.01.2025

Lugar, fecha / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Nombre y cargo / *Name and function*

DÉCLARATION DE CONFORMITÉ / *DECLARATION OF CONFORMITY*

Nom et adresse de la société / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Allemagne / *Germany* *SRN: DE-MF-000007705*

Nous déclarons sous notre seule responsabilité que / *We declare under our sole responsibility that*

le dispositif médical / *the medical device*	Paladur
Nom, type ou modèle, numéro de lot ou de série, éventuellement sources et nombre d'articles / *Name, type or model, batch or serial number, possibly sources and number of items*	Liste des articles voir l'Annexe / *List of Articles see Annex*
Code EMDN / *EMDN-Code* Code GMDN / *GMDN code* code UMDNS / *UMDNS code* UDI-DI de base / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699mBC
de classe / *of class*	IIa
selon la règle / *according to rule*	5-3, 19-3 conformément à l'Annexe VIII du Règlement des Dispositifs Médicaux 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

répond à toutes les dispositions du Règlement des Dispositifs Médicaux 2017/745 qui lui sont applicables. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Application de normes harmonisées, de normes nationales ou d'autres documents normatifs / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Autres normes appliquées voir Documentation technique du produit Paladur, version 04 *Further Applied standards see Technical Documentation of Product Paladur, Version 04*
Procédure d'évaluation de la conformité selon / *Conformity assessment procedure acc. to*	Règlement relatif aux dispositifs médicaux 2017/745 Annexe IX, Chapitre I, Paragraphes 2 et 3 et Chapitre III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organisme notifié / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Allemagne CE 0197
Numéro d'enregistrement / *Registration number:*	HZ 1198082-1
Numéro de version / *Version number*	03
Remplace la Déclaration de conformité de / *Replaces Declaration of Conformity from*	04.01.2023
Hanau, 02.01.2025	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Lieu, date / *Place, date*	Nom et fonction / *Name and function*

Cette déclaration de conformité est valable 2 ans en relation avec les documents de libération pour le lot respectif des dispositifs médicaux fabriqués. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Déclaration de conformité / *Declaration of Conformity*
Annexe / *Annex* : Liste des articles / *List of Articles*

Le dispositif médical / *The medical device*	Paladur
Numéro de version / *Version number*	02
Remplace l'annexe de / *Replaces Annex from*	04.01.2023
Cette liste d'articles est valable pour la déclaration de conformité, version / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Numéro de référence / *Article number***	**Nom / *Name***
+J014647079370	64707937	Paladur, 80 ml DE/IT
+J014647079380	64707938	Paladur, 500 ml DE/GB/FR/NL
+J014647079450	64707945	Paladur, rosa, 100 g
+J014647079480	64707948	Paladur, farblos, 100 g
+J014647079540	64707954	Paladur, rosa, 500 g
+J014647079560	64707956	Paladur, 500 g, rosa geadert
+J014647079570	64707957	Paladur, farblos, 500 g
+J014647079630	64707963	Paladur, rosa, 1000 g
+J014647079650	64707965	Paladur, rosa geadert, 1000 g
+J014647079660	64707966	Paladur, farblos, 1000 g
+J014647079670	64707967	Paladur, R 50 geadert, 1000 g
+J014660707260	66070726	Paladur, 500ml IT/ES/DK/GR/SK

Hanau, 02.01.2025

Lieu, date / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Nom et fonction / *Name and function*

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ / *DECLARATION OF CONFORMITY*

Επωνυμία και διεύθυνση εταιρείας / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Γερμανία / *Germany* *SRN: DE-MF-000007705*

Δηλώνουμε με δική μας ευθύνη ότι / *We declare under our sole responsibility that*

το ιατροτεχνολογικό προϊόν / *the medical device*	Paladur
Επωνυμία, τύπος ή μοντέλο, παρτίδα ή αριθμός σειράς, πιθανές πηγές και αριθμός ειδών / *Name, type or model, batch or serial number, possibly sources and number of items*	Κατάλογος ειδών Παράρτημα / *List of Articles see Annex*
Κωδικός EMDN / *EMDN-Code* Κωδικός GMDN / *GMDN code* Κωδικός UMDNS / *UMDNS code* Βασικό UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699mBC
κλάσης / *of class*	IIa
σύμφωνα με τον κανόνα / *according to rule*	5-3, 19-3 σύμφωνα με το Παράρτημα VIII του Κανονισμού 2017/745 για τα ιατροτεχνολογικά προϊόντα / *according to Annex VIII of Medical Device Regulation 2017/745*

πληροί όλες τις ισχύουσες διατάξεις του Κανονισμού 2017/745 για τα ιατροτεχνολογικά προϊόντα. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Εφαρμοζόμενα εναρμονισμένα πρότυπα, εθνικά πρότυπα ή άλλα κανονιστικά έγγραφα / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική τεκμηρίωση του Προϊόντος Paladur, έκδοση 04 *Further Applied standards see Technical Documentation of Product Paladur, Version 04*
Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με / *Conformity assessment procedure acc. to*	Κανονισμός 2017/745 για τα ιατροτεχνολογικά προϊόντα, Παράρτημα IX, Κεφάλαιο I, Τμήμα 2 και 3, και Κεφάλαιο III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Κοινοποιημένος οργανισμός / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Γερμανία CE 0197
Αριθμός καταχώρησης / *Registration number:*	HZ 1198082-1
Αριθμός έκδοσης / *Version number*	03
Αντικαθιστά τη δήλωση συμμόρφωσης από / *Replaces Declaration of Conformity from*	04.01.2023
Hanau, 02.01.2025	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Τόπος, ημερομηνία / *Place, date*	Ονοματεπώνυμο και τίτλος / *Name and function*

Αυτή η δήλωση συμμόρφωσης ισχύει για 2 χρόνια σε σχέση με τα έγγραφα κυκλοφορίας για την αντίστοιχη παρτίδα των παραγόμενων προϊόντων. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Κατάλογος ειδών / *List of Articles*
Παράρτημα / *Annex*: Δήλωση συμμόρφωσης / *Declaration of Conformity*

Το ιατροτεχνολογικό προϊόν / *The medical device*	Paladur
Αριθμός έκδοσης / *Version number*	02
Αντικαθιστά το Παράρτημα από / *Replaces Annex from*	04.01.2023
Αυτός ο κατάλογος προϊόντων ισχύει για την έκδοση δήλωσης συμμόρφωσης / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Αριθμός είδους / *Article number***	**Όνομα / *Name***
+J014647079370	64707937	Paladur, 80 ml DE/IT
+J014647079380	64707938	Paladur, 500 ml DE/GB/FR/NL
+J014647079450	64707945	Paladur, rosa, 100 g
+J014647079480	64707948	Paladur, farblos, 100 g
+J014647079540	64707954	Paladur, rosa, 500 g
+J014647079560	64707956	Paladur, 500 g, rosa geadert
+J014647079570	64707957	Paladur, farblos, 500 g
+J014647079630	64707963	Paladur, rosa, 1000 g
+J014647079650	64707965	Paladur, rosa geadert, 1000 g
+J014647079660	64707966	Paladur, farblos, 1000 g
+J014647079670	64707967	Paladur, R 50 geadert, 1000 g
+J014660707260	66070726	Paladur, 500ml IT/ES/DK/GR/SK

Hanau, 02.01.2025

Τόπος, ημερομηνία / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Ονοματεπώνυμο και τίτλος / *Name and function*

DICHIARAZIONE DI CONFORMITÀ / *DECLARATION OF CONFORMITY*

Nome e indirizzo della società / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Germania / *Germany* *SRN: DE-MF-000007705*

Dichiariamo sotto la nostra esclusiva responsabilità che /
We declare under our sole responsibility that

il dispositivo medico / *the medical device*	Paladur
Nome, tipo o modello, numero di lotto o di serie, eventualmente fonti e numero di articoli / *Name, type or model, batch or serial number, possibly sources and number of items*	Elenco degli articoli vedi allegato / *List of Articles see Annex*
Codice EMDN / *EMDN-Code* Codice GMDN / *GMDN code* Codice UMDNS / *UMDNS code* UDI-DI di base / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699mBC
di classe / *of class*	IIa
secondo la norma / *according to rule*	5-3, 19-3 secondo l'allegato VIII del regolamento sui dispositivi medici 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

soddisfa tutte le disposizioni del regolamento sui dispositivi medici 2017/745 ad esso applicabili. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Norme armonizzate applicate, norme nazionali o altri documenti normativi / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Ulteriori norme applicate vedi Documentazione tecnica di Prodotto Paladur, Versione 04 *Further Applied standards see Technical Documentation of Product Paladur, Version 04*
Procedura di valutazione della conformità secondo il / *Conformity assessment procedure acc. to*	Regolamento sui dispositivi medici 2017/745 Allegato IX, Capitolo I, Paragrafi 2 e 3, e Capitolo III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organismo notificato / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Norimberga / Germania CE 0197
Numero di registrazione / *Registration number:*	HZ 1198082-1
Numero versione / *Version number*	03
Sostituisce la dichiarazione di conformità di / *Replaces Declaration of Conformity from*	04.01.2023
Hanau, 02.01.2025	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Luogo, data / *Place, date*	Nome e funzione / *Name and function*

La presente dichiarazione di conformità ha validità di 2 anni in relazione ai documenti di rilascio per il lotto corrispondente di dispositivi prodotti. */ This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Elenco degli articoli / *List of Articles*
Allegato / *Annex*: Dichiarazione di conformità / *Declaration of Conformity*

Il dispositivo medico / *The medical device*	Paladur
Numero versione / *Version number*	02
Sostituisce l'allegato da / *Replaces Annex from*	04.01.2023
Questa lista di articoli è valida per la versione della dichiarazione di conformità / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Numero articolo / *Article number***	**Nome / *Name***
+J014647079370	64707937	Paladur, 80 ml DE/IT
+J014647079380	64707938	Paladur, 500 ml DE/GB/FR/NL
+J014647079450	64707945	Paladur, rosa, 100 g
+J014647079480	64707948	Paladur, farblos, 100 g
+J014647079540	64707954	Paladur, rosa, 500 g
+J014647079560	64707956	Paladur, 500 g, rosa geadert
+J014647079570	64707957	Paladur, farblos, 500 g
+J014647079630	64707963	Paladur, rosa, 1000 g
+J014647079650	64707965	Paladur, rosa geadert, 1000 g
+J014647079660	64707966	Paladur, farblos, 1000 g
+J014647079670	64707967	Paladur, R 50 geadert, 1000 g
+J014660707260	66070726	Paladur, 500ml IT/ES/DK/GR/SK

Hanau, 02.01.2025

Luogo, data / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Nome e funzione / *Name and function*

VERKLARING VAN CONFORMITEIT / *DECLARATION OF CONFORMITY*

Naam en adres van de onderneming / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Duitsland / *Germany* *SRN: DE-MF-000007705*

Wij verklaren geheel onder onze eigen verantwoordelijkheid dat /
We declare under our sole responsibility that

het medisch hulpmiddel / *the medical device*	Paladur
Naam, type of model, batch of serienummer, mogelijke bronnen en aantal items / *Name, type or model, batch or serial number, possibly sources and number of items*	Voor lijst met artikelen, zie bijlage / *List of Articles see Annex*
EMDN-code / *EMDN-Code* GMDN-code / *GMDN code* UMDNS-code / *UMDNS code* Basis UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699mBC
van klasse / *of class*	IIa
in overeenstemming met regelgeving / *according to rule*	5-3, 19-3 conform Bijlage VIII van de Verordening (EU) 2017/745 betreffende medische hulpmiddelen / *according to Annex VIII of Medical Device Regulation 2017/745*

voldoet aan alle voorschriften van de Verordening (EU) 2017/745 betreffende medische hulpmiddelen die erop van toepassing zijn. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Toegepaste geharmoniseerde normen, nationale normen of andere normatieve documenten / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Voor overige toegepaste normen, zie technische documenten van product Paladur, versie 04 *Further Applied standards see Technical Documentation of Product Paladur, Version 04*
Conformiteitsbeoordelingsprocedure in overeenstemming met / *Conformity assessment procedure acc. to*	Verordening (EU) 2017/745 betreffende medische hulpmiddelen bijlage IX, hoofdstuk I, sectie 2 en 3 en hoofdstuk III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Aangemelde instantie / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Duitsland CE 0197
Registratienummer / *Registration number:*	HZ 1198082-1
Versienummer / *Version number*	03
Vervangt de verklaring van conformiteit van / *Replaces Declaration of Conformity from*	04.01.2023
Hanau, 02.01.2025	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Plaats, datum / *Place, date*	Naam en functie / *Name and function*

Deze conformiteitsverklaring is 2 jaar geldig in verband met de vrijgavedocumenten voor de respectieve partij van geproduceerde hulpmiddelen. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Lijst met artikelen / *List of Articles*
Annex / *Annex*: Verklaring van conformiteit / *Declaration of Conformity*

Het medisch hulpmiddel / *The medical device*	Paladur
Versienummer / *Version number*	02
Vervangt de bijlage van / *Replaces Annex from*	04.01.2023
Deze artikellijst is geldig voor de conformiteitsverklaring, versie / *This article list is valid for the declaration of conformity version*	03

Unieke identificatiecode / *UDI-DI*	**Artikelnummer / *Article number***	**Naam / *Name***
+J014647079370	64707937	Paladur, 80 ml DE/IT
+J014647079380	64707938	Paladur, 500 ml DE/GB/FR/NL
+J014647079450	64707945	Paladur, rosa, 100 g
+J014647079480	64707948	Paladur, farblos, 100 g
+J014647079540	64707954	Paladur, rosa, 500 g
+J014647079560	64707956	Paladur, 500 g, rosa geadert
+J014647079570	64707957	Paladur, farblos, 500 g
+J014647079630	64707963	Paladur, rosa, 1000 g
+J014647079650	64707965	Paladur, rosa geadert, 1000 g
+J014647079660	64707966	Paladur, farblos, 1000 g
+J014647079670	64707967	Paladur, R 50 geadert, 1000 g
+J014660707260	66070726	Paladur, 500ml IT/ES/DK/GR/SK

Hanau, 02.01.2025

Plaats, datum / *Place, date*

i.V. Matthias Hartmann

i.V Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Naam en functie / *Name and function*

KULZER
MITSUI CHEMICALS GROUP

VYHLÁSENIE O ZHODE / *DECLARATION OF CONFORMITY*

Názov a adresa spoločnosti / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Nemecko / *Germany* *SRN: DE-MF-000007705*

Vyhlasujeme na svoju výlučnú zodpovednosť, že / *We declare under our sole responsibility that*

zdravotnícka pomôcka / *the medical device*	Paladur
Názov, typ alebo model, číslo šarže alebo sériové číslo, prípadne zdroje a počet kusov / *Name, type or model, batch or serial number, possibly sources and number of items*	Zoznam položiek je uvedený v prílohe / *List of Articles see Annex*
Kód EMDN / *EMDN-Code* Kód GMDN / *GMDN code* Kód UMDNS / *UMDNS code* Základné identifikačné číslo UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699mBC
triedy / *of class*	IIa
podľa pravidla / *according to rule*	5-3, 19-3 podľa prílohy VIII k nariadeniu 2017/745 o zdravotníckych pomôckach / *according to Annex VIII of Medical Device Regulation 2017/745*

spĺňa všetky ustanovenia nariadenia 2017/745 o zdravotníckych pomôckach, ktoré sa na ňu vzťahujú. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Použité harmonizované normy, národné normy alebo iné normatívne dokumenty / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Ďalšie použité normy nájdete v technickej dokumentácii verzie 04 k produktu Paladur *Further Applied standards see Technical Documentation of Product Paladur, Version 04*
Postup posúdenia zhody podľa / *Conformity assessment procedure acc. to*	prílohy IX k nariadeniu 2017/745 o zdravotníckych pomôckach, kapitola I, časť 2 a 3 a kapitola III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikovaný orgán / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Nemecko CE 0197
Registračné číslo / *Registration number:*	HZ 1198082-1
Číslo verzie / *Version number*	03
Nahrádza vyhlásenie o zhode z / *Replaces Declaration of Conformity from*	04.01.2023
Hanau, 02.01.2025 Miesto, dátum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Meno a funkcia / *Name and function*

Toto vyhlásenie o zhode je platné 2 roky v súvislosti s dokumentmi o uvoľnení príslušnej šarže vyrobených pomôcok. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Zoznam položiek / *List of Articles*
Príloha / *Annex*: Vyhlásenie o zhode / *Declaration of Conformity*

Zdravotnícka pomôcka / *The medical device*	Paladur
Číslo verzie / *Version number*	02
Nahrádza prílohu z / *Replaces Annex from*	04.01.2023
Tento zoznam tovaru je platný pre vyhlásenie o zhode, verzia / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Číslo položky / *Article number***	**Meno / *Name***
+J014647079370	64707937	Paladur, 80 ml DE/IT
+J014647079380	64707938	Paladur, 500 ml DE/GB/FR/NL
+J014647079450	64707945	Paladur, rosa, 100 g
+J014647079480	64707948	Paladur, farblos, 100 g
+J014647079540	64707954	Paladur, rosa, 500 g
+J014647079560	64707956	Paladur, 500 g, rosa geadert
+J014647079570	64707957	Paladur, farblos, 500 g
+J014647079630	64707963	Paladur, rosa, 1000 g
+J014647079650	64707965	Paladur, rosa geadert, 1000 g
+J014647079660	64707966	Paladur, farblos, 1000 g
+J014647079670	64707967	Paladur, R 50 geadert, 1000 g
+J014660707260	66070726	Paladur, 500ml IT/ES/DK/GR/SK

Hanau, 02.01.2025

Miesto, dátum / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Meno a funkcia / *Name and function*

Abschlusszertifikat

Umschlag-ID: 3CC687D4-4F98-45C8-8604-935167048EC8
Status: Abgeschlossen
Betreff: Mit Docusign abschließen: # 3-01 Paladur_DoC_V03 + Annex_V02.pdf
Quellumschlag:
Dokumentenseiten: 16
Signaturen: 16
Zertifikatsseiten: 1
Initialen: 0
Signatur mit Anleitung: Aktiviert
Umschlag-ID-Stempel: Aktiviert
Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien

Umschlagersteller:
Insa Deckardt
Leipziger Str. 2
Hanau, Hessen 63450
insa.deckardt@kulzer-dental.com
IP-Adresse: 52.233.243.152

Eintragsverfolgung

Status: Original
02.01.2025 09:46:05
Inhaber: Insa Deckardt
insa.deckardt@kulzer-dental.com
Standort: DocuSign

Unterzeichnerereignisse	Signatur	Zeitstempel
Matthias Hartmann matthias.hartmann@kulzer-dental.com Head of Global Quality, Regulatory & Scientific Services Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	 Signaturübernahme: Hochgeladenes Signaturbild Mit IP-Adresse: 77.181.124.143	Gesendet: 02.01.2025 09:49:46 Eingesehen: 02.01.2025 14:32:42 Signiert: 02.01.2025 14:33:10

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:
Nicht über DocuSign angeboten

Vor-Ort-Unterzeichner – Ereignisse	Signatur	Zeitstempel

Bearbeiterversandereignisse	Status	Zeitstempel

Beauftragtenzustellereignisse	Status	Zeitstempel

Vermittlerversandereignisse	Status	Zeitstempel

Zertifizierter Versand - Ereignisse	Status	Zeitstempel

Kopienereignisse	Status	Zeitstempel

Zeugen-Ereignisse	Signatur	Zeitstempel

Notarereignisse	Signatur	Zeitstempel

Umschlagereignisse – Überblick	Status	Zeitstempel
Umschlag gesendet	Hash-codiert/verschlüsselt	02.01.2025 09:49:46
Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	02.01.2025 14:32:42
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	02.01.2025 14:33:10
Abgeschlossen	Sicherheitsprüfung ausgeführt	02.01.2025 14:33:10

Zahlungen	Status	Zeitstempel