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*	**Paladon 65**
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 ++J0141209DEBM0699aAL
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 03 der Technischen Dokumentation von Product Paladon 65 / *Further Applied standards see Technical Documentation of Product Paladon 65, Version 03*
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*	15.11.2022
Hanau, 11.11.2024 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*	**Paladon 65**
Versionsnummer Artikelliste / *Version number article list*	02
Ersetzt Artikelliste vom / *Replaces article list from*	15.11.2022
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***
+J014647076730	64707673	Paladon 65, 80 ml DE/IT
+J014647076740	64707674	Paladon 65, 500 ml DE/GB/FR/NL
+J014647076870	64707687	Paladon 65, rosa, 100 g
+J014647076990	64707699	Paladon 65, rosa, 500 g
+J014647077060	64707706	Paladon 65, rosa, 1000 g
+J014647077080	64707708	Paladon 65, rosa geadert,1000 g
+J014647077100	64707710	Paladon 65, farblos, 1000 g
+J014647077110	64707711	Paladon 65, R 50 geadert, 1000 g
+J014660707400	66070740	Paladon 65, 500ml IT/ES/DK/GR/CZ/HR

Hanau, 11.11.2024

Ort, Datum / *Place, date*

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

Name und Funktion / *Name and function*

PROHLÁŠENÍ O SHODĚ / *DECLARATION OF CONFORMITY*

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

Prohlašujeme na svou výlučnou zodpovědnost, že / *We declare under our sole responsibility that*

zdravotnický prostředek / *the medical device*	**Paladon 65**
Název, typ nebo model, šarže nebo výrobní číslo, případně zdroje a počet kusů / *Name, type or model, batch or serial number, possibly sources and number of items*	Seznam položek je uveden v příloze / *List of Articles see Annex*
Kód EMDN / *EMDN-Code* Kód GMDN / *GMDN code* Kód UMDNS / *UMDNS code* Základní UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699aAL
třídy / *of class*	IIa
podle pravidla / *according to rule*	5-3, 19-3 podle přílohy VIII k nařízení 2017/745 o zdravotnických prostředcích / *according to Annex VIII of Medical Device Regulation 2017/745*

splňuje všechna ustanovení nařízení 2017/745 o zdravotnických prostředcích, která se ho týkají. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Použité harmonizované normy, národní normy nebo jiné normativní dokumenty / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Další použité normy najdete v technické dokumentaci k Výrobku Paladon 65, verze 03 *Further Applied standards see Technical Documentation of Product Paladon 65, Version 03*
Procedura posouzení shody podle / *Conformity assessment procedure acc. to*	nařízení 2017/745 o zdravotnických prostředcích, příloha IX, kapitola I, oddíl 2 a 3 a kapitola III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikovaná osoba / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Německo CE 0197
Registrační číslo / *Registration number*:	HZ 1198082-1
Číslo verze / *Version number*	03
Nahrazuje Prohlášení o shodě ze dne / *Replaces Declaration of Conformity from*	15.11.2022
Hanau, 11.11.2024	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Místo, datum / *Place, date*	Jméno a funkce / *Name and function*

Toto prohlášení o shodě je platné po dobu 2 let ve spojení s příbalovými informacemi pro příslušnou šarži vyrobených zdravotnických prostředků. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices*.

KULZER
MITSUI CHEMICALS GROUP

Seznam položek / *List of Articles*
Příloha / *Annex*: Prohlášení o shodě / *Declaration of Conformity*

Zdravotnický prostředek / *The medical device*	**Paladon 65**
Číslo verze / *Version number*	02
Nahrazuje přílohu ze dne / *Replaces Annex from*	15.11.2022
Tento seznam zboží platí pro verzi prohlášení o shodě / *This article list is valid for the declaration of conformity version:*	03

UDI-DI / *UDI-DI*	**Číslo zboží / *Article number***	**Název / *Name***
+J014647076730	64707673	Paladon 65, 80 ml DE/IT
+J014647076740	64707674	Paladon 65, 500 ml DE/GB/FR/NL
+J014647076870	64707687	Paladon 65, rosa, 100 g
+J014647076990	64707699	Paladon 65, rosa, 500 g
+J014647077060	64707706	Paladon 65, rosa, 1000 g
+J014647077080	64707708	Paladon 65, rosa geadert,1000 g
+J014647077100	64707710	Paladon 65, farblos, 1000 g
+J014647077110	64707711	Paladon 65, R 50 geadert, 1000 g
+J014660707400	66070740	Paladon 65, 500ml IT/ES/DK/GR/CZ/HR

Hanau, 11.11.2024

Místo, datum / *Place, date*

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

Jméno a funkce / *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*	**Paladon 65**
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 ++J0141209DEBM0699aAL
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 Paladon 65, version 03 *Further Applied standards see Technical Documentation of Product Paladon 65, Version 03*
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*	15.11.2022
Hanau, 11.11.2024 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*

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*	**Paladon 65**
Versionsnummer / *Version number*	02
Erstatter bilag fra / *Replaces Annex from*	15.11.2022
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***
+J014647076730	64707673	Paladon 65, 80 ml DE/IT
+J014647076740	64707674	Paladon 65, 500 ml DE/GB/FR/NL
+J014647076870	64707687	Paladon 65, rosa, 100 g
+J014647076990	64707699	Paladon 65, rosa, 500 g
+J014647077060	64707706	Paladon 65, rosa, 1000 g
+J014647077080	64707708	Paladon 65, rosa geadert,1000 g
+J014647077100	64707710	Paladon 65, farblos, 1000 g
+J014647077110	64707711	Paladon 65, R 50 geadert, 1000 g
+J014660707400	66070740	Paladon 65, 500ml IT/ES/DK/GR/CZ/HR

Hanau, 11.11.2024

Sted, dato / *Place, date*

i.V. Matthias Hartmann

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*	**Paladon 65**
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 ++J0141209DEBM0699aAL
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 Paladon 65, versión 03 *Further Applied standards see Technical Documentation of Product Paladon 65, Version 03*
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*	15.11.2022
Hanau, 11.11.2024 Lugar, fecha / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** 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*	**Paladon 65**
Número de versión / *Version number*	02
Sustituye al Anexo del / *Replaces Annex from*	15.11.2022
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***
+J014647076730	64707673	Paladon 65, 80 ml DE/IT
+J014647076740	64707674	Paladon 65, 500 ml DE/GB/FR/NL
+J014647076870	64707687	Paladon 65, rosa, 100 g
+J014647076990	64707699	Paladon 65, rosa, 500 g
+J014647077060	64707706	Paladon 65, rosa, 1000 g
+J014647077080	64707708	Paladon 65, rosa geadert,1000 g
+J014647077100	64707710	Paladon 65, farblos, 1000 g
+J014647077110	64707711	Paladon 65, R 50 geadert, 1000 g
+J014660707400	66070740	Paladon 65, 500ml IT/ES/DK/GR/CZ/HR

Hanau, 11.11.2024

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*	**Paladon 65**
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 ++J0141209DEBM0699aAL
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 Paladon 65, version 03 *Further Applied standards see Technical Documentation of Product Paladon 65 Version 03*
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*	22.12.2022
Hanau, 11.11.2024 Lieu, date / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** 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*	**Paladon 65**
Numéro de version / *Version number*	02
Remplace l'annexe de / *Replaces Annex from*	15.11.2022
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***
+J014647076730	64707673	Paladon 65, 80 ml DE/IT
+J014647076740	64707674	Paladon 65, 500 ml DE/GB/FR/NL
+J014647076870	64707687	Paladon 65, rosa, 100 g
+J014647076990	64707699	Paladon 65, rosa, 500 g
+J014647077060	64707706	Paladon 65, rosa, 1000 g
+J014647077080	64707708	Paladon 65, rosa geadert,1000 g
+J014647077100	64707710	Paladon 65, farblos, 1000 g
+J014647077110	64707711	Paladon 65, R 50 geadert, 1000 g
+J014660707400	66070740	Paladon 65, 500ml IT/ES/DK/GR/CZ/HR

Hanau, 11.11.2024

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*	**Paladon 65**
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 ++J0141209DEBM0699aAL
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 Paladon 65, έκδοση 03 *Further Applied standards see Technical Documentation of Product Paladon 65, Version 03*
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*	15.11.2022
Hanau, 11.11.2024 Τόπος, ημερομηνία / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** 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.*

KULZER
MITSUI CHEMICALS GROUP

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

Το ιατροτεχνολογικό προϊόν / *The medical device*	**Paladon 65**
Αριθμός έκδοσης / *Version number*	02
Αντικαθιστά το Παράρτημα από / *Replaces Annex from*	15.11.2022
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***
+J014647076730	64707673	Paladon 65, 80 ml DE/IT
+J014647076740	64707674	Paladon 65, 500 ml DE/GB/FR/NL
+J014647076870	64707687	Paladon 65, rosa, 100 g
+J014647076990	64707699	Paladon 65, rosa, 500 g
+J014647077060	64707706	Paladon 65, rosa, 1000 g
+J014647077080	64707708	Paladon 65, rosa geadert,1000 g
+J014647077100	64707710	Paladon 65, farblos, 1000 g
+J014647077110	64707711	Paladon 65, R 50 geadert, 1000 g
+J014660707400	66070740	Paladon 65, 500ml IT/ES/DK/GR/CZ/HR

Hanau, 11.11.2024

Τόπος, ημερομηνία / *Place, date*

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

Ονοματεπώνυμο και τίτλος / *Name and function*

KULZER
MITSUI CHEMICALS GROUP

IZJAVA O USKLAĐENOSTI / *DECLARATION OF CONFORMITY*

Naziv i adresa tvrtke / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Njemačka / *Germany* *SRN: DE-MF-000007705*

Izjavljujemo pod punom odgovornošću da / *We declare under our sole responsibility that*

medicinski proizvod / *the medical device*	**Paladon 65**
Naziv, tip ili model, broj serije, po mogućnosti izvori i broj stavki / *Name, type or model, batch or serial number, possibly sources and number of items*	Popis artikala, pogledajte Dodatak / *List of Articles see Annex*
šifra EMDN / *EMDN-Code* šifra GMDN / *GMDN code* šifra UMDNS / *UMDNS code* osnovni UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699aAL
klase / *of class*	IIa
u skladu s pravilom / *according to rule*	5-3, 19-3 u skladu s Dodatkom VIII Uredbe 2017/745 o medicinskim proizvodima / *according to Annex VIII of Medical Device Regulation 2017/745*

ispunjava sve odredbe Uredbe 2017/745 o medicinskim proizvodima koje se na njega odnose. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Primijenjene usklađene norme, državne norme ili drugi normativni dokumenti / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod Paladon 65, verzija 03 *Further Applied standards see Technical Documentation of Product Paladon 65, Version 03*
Postupak procjene usklađenosti prema / *Conformity assessment procedure acc. to*	Prilog IX Uredbi 2017/745 o medicinskim proizvodima, Poglavlje I, Odjeljak 2 i 3 te Poglavlje III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Obaviješteno tijelo / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Njemačka CE 0197
Registracijski broj / *Registration number*:	HZ 1198082-1
Broj verzije / *Version number*	03
Zamjenjuje Izjavu o usklađenosti od / *Replaces Declaration of Conformity from*	15.11.2022
Hanau, 11.11.2024	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Mjesto, datum / *Place, date*	Ime i funkcija / *Name and function*

Ova Izjava o usklađenosti valjana je 2 godine u odnosu na dokumente o izdanju za odgovarajuće serije proizvedenih umedicinskih proizvoda. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Popis artikala / *List of Articles*
Dodatak / *Annex*: Izjava o usklađenosti / *Declaration of Conformity*

Medicinski proizvod / *The medical device*	**Paladon 65**
Broj verzije / *Version number*	02
Zamjenjuje Dodatak od / *Replaces Annex from*	15.11.2022
Ovaj popis artikala valjan je za verziju izjave u sukladnosti / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Broj artikla / *Article number***	**Naziv / *Name***
+J014647076730	64707673	Paladon 65, 80 ml DE/IT
+J014647076740	64707674	Paladon 65, 500 ml DE/GB/FR/NL
+J014647076870	64707687	Paladon 65, rosa, 100 g
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+J014647077080	64707708	Paladon 65, rosa geadert,1000 g
+J014647077100	64707710	Paladon 65, farblos, 1000 g
+J014647077110	64707711	Paladon 65, R 50 geadert, 1000 g
+J014660707400	66070740	Paladon 65, 500ml IT/ES/DK/GR/CZ/HR

Hanau, 11.11.2024

Mjesto, datum / *Place, date*

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

Ime i funkcija / *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*	**Paladon 65**
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 ++J0141209DEBM0699aAL
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 Paladon 65, Versione 03 *Further Applied standards see Technical Documentation of Product Paladon 65, Version 03*
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*	15.11.2022
Hanau, 11.11.2024 Luogo, data / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** 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*	**Paladon 65**
Numero versione / *Version number*	02
Sostituisce l'allegato da / *Replaces Annex from*	15.11.2022
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***
+J014647076730	64707673	Paladon 65, 80 ml DE/IT
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+J014647077060	64707706	Paladon 65, rosa, 1000 g
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+J014647077100	64707710	Paladon 65, farblos, 1000 g
+J014647077110	64707711	Paladon 65, R 50 geadert, 1000 g
+J014660707400	66070740	Paladon 65, 500ml IT/ES/DK/GR/CZ/HR

Hanau, 11.11.2024

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*	**Paladon 65**
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 ++J0141209DEBM0699aAL
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 Paladon 65, versie 03 *Further Applied standards see Technical Documentation of Product Paladon 65, Version 03*
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*	15.11.2022
Hanau, 11.11.2024 Plaats, datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** 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*	**Paladon 65**
Versienummer / *Version number*	02
Vervangt de bijlage van / *Replaces Annex from*	15.11.2022
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***
+J014647076730	64707673	Paladon 65, 80 ml DE/IT
+J014647076740	64707674	Paladon 65, 500 ml DE/GB/FR/NL
+J014647076870	64707687	Paladon 65, rosa, 100 g
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+J014647077100	64707710	Paladon 65, farblos, 1000 g
+J014647077110	64707711	Paladon 65, R 50 geadert, 1000 g
+J014660707400	66070740	Paladon 65, 500ml IT/ES/DK/GR/CZ/HR

Hanau, 11.11.2024

Plaats, datum / *Place, date*

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

Naam en functie / *Name and function*