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*	PalaXpress
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 ++J0141209DEBM0699fAW
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 PalaXpress / *Further Applied standards see Technical Documentation of Product PalaXpress, 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*	04.01.2023
Hanau, 23.12.2024 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*	PalaXpress
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***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
+J014647105160	64710516	PalaXpress, rosa geadert, 1000g Pulver
+J014647113980	64711398	PalaXpress, R50 geadert, 1000g Pulver
+J014647114850	64711485	PalaXpress, farblos, 1000g Pulver
+J014647116300	64711630	PalaXpress, rosa, 100g Pulver
+J014647116310	64711631	PalaXpress, 80ml DE/IT
+J014647116930	64711693	PalaXpress, farblos, 100g Pulver
+J014647122450	64712245	PalaXpress, life pink, 1000g
+J014647124320	64712432	PalaXpress, rosa, 12000g Pulver
+J014647127630	64712763	PalaXpress, rosa opak, 100g Pulver
+J014647127640	64712764	PalaXpress, rosa opak, 1000g Pulver
+J014647149910	64714991	PalaXpress, rosa geadert, 100g Pulver
+J014647149920	64714992	PalaXpress, R50 geadert, 100g Pulver
+J014660201110	66020111	PalaXpress, pink live, 1000g Pulver
+J014660201120	66020112	PalaXpress, pink live, 100g Pulver
+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

Ort, Datum / *Place, date*

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

Name und Funktion / *Name and function*

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*	PalaXpress
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 ++J0141209DEBM0699fAW
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 PalaXpress, versión 03 *Further Applied standards see Technical Documentation of Product PalaXpress, 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*	04.01.2023

Hanau, 23.12.2024

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*	PalaXpress
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***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
+J014647105160	64710516	PalaXpress, rosa geadert, 1000g Pulver
+J014647113980	64711398	PalaXpress, R50 geadert, 1000g Pulver
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+J014647116300	64711630	PalaXpress, rosa, 100g Pulver
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+J014647124320	64712432	PalaXpress, rosa, 12000g Pulver
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+J014660201120	66020112	PalaXpress, pink live, 100g Pulver
+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

Lugar, fecha / *Place, date*

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

Nombre y cargo / *Name and function*

VAATIMUSTENMUKAISUUSVAKUUTUS / *DECLARATION OF CONFORMITY*

Yhtiön nimi ja osoite / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Saksa / *Germany* *SRN: DE-MF-000007705*

Vakuutamme yksinomaisella vastuullamme, että / *We declare under our sole responsibility that*

lääkinnällinen laite / *the medical device*	PalaXpress
Laitteen nimi, tyyppi tai malli, erä- tai sarjanumero, mahdolliset lähteet ja lukumäärä / *Name, type or model, batch or serial number, possibly sources and number of items*	Artikkeliluettelo, ks. liite / *List of Articles see Annex*
EMDN-koodi / *EMDN-Code* GMDN-koodi / *GMDN code* UMDNS-koodi / *UMDNS code* Perus-UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699fAW
luokka / *of class*	IIa
säädös / *according to rule*	5-3, 19-3 lääkinnällisistä laitteista annetun asetuksen 2017/745 liitteen VIII mukaan / *according to Annex VIII of Medical Device Regulation 2017/745*

täyttää kaikki lääkinnällisistä laitteista annetun asetuksen 2017/745 soveltuvat vaatimukset. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Soveltuvat harmonisoidut standardit, kansalliset standardit tai muut säädökset / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Muut sovellettavat standardit, ks. tekniset tiedot tuotteesta PalaXpress, versio 03 *Further Applied standards see Technical Documentation of Product PalaXpress, Version 03*
Vaatimustenmukaisuuden arviointimenettelyn perusta / *Conformity assessment procedure acc. to*	Asetus lääkinnällisistä laitteista 2017/745, liite IX, I luku, 2 ja 3 kohta ja III luku *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Ilmoitettu laitos / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Saksa CE 0197
Rekisteröintinumero / *Registration number:*	HZ 1198082-1
Versionumero / *Version number*	03
Korvaa vaatimustenmukaisuusvakuutuksen / *Replaces Declaration of Conformity from*	04.01.2023
Hanau, 23.12.2024	i.V Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Paikka, päiväys / *Place, date*	Nimi ja asema / *Name and function*

Tämä vaatimustenmukaisuusvakuutus on voimassa 2 vuotta tuotettujen laitteiden vastaavan erän julkaisuasiakirjojen kanssa. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Artikkeliluettelo / *List of Articles*
Liite / *Annex*: Vaatimustenmukaisuusvakuutus / *Declaration of Conformity*

Lääkinnällinen laite / *The medical device*	PalaXpress
Versionumero / *Version number*	02
Korvaa liitteen / *Replaces Annex from*	04.01.2023
Tämä artikkeliluettelo pätee vaatimustenmukaisuusvakuutuksen versioon / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Artikkelinumero / *Article number***	**Nimi / *Name***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
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+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

Paikka, päiväys / *Place, date*

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

Nimi ja asema / *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*	PalaXpress
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 ++J0141209DEBM0699fAW
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 PalaXpress, version 03 *Further Applied standards see Technical Documentation of Product* PalaXpress*, 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*	04.01.2023
Hanau, 23.12.2024 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*	PalaXpress
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***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
+J014647105160	64710516	PalaXpress, rosa geadert, 1000g Pulver
+J014647113980	64711398	PalaXpress, R50 geadert, 1000g Pulver
+J014647114850	64711485	PalaXpress, farblos, 1000g Pulver
+J014647116300	64711630	PalaXpress, rosa, 100g Pulver
+J014647116310	64711631	PalaXpress, 80ml DE/IT
+J014647116930	64711693	PalaXpress, farblos, 100g Pulver
+J014647122450	64712245	PalaXpress, life pink, 1000g
+J014647124320	64712432	PalaXpress, rosa, 12000g Pulver
+J014647127630	64712763	PalaXpress, rosa opak, 100g Pulver
+J014647127640	64712764	PalaXpress, rosa opak, 1000g Pulver
+J014647149910	64714991	PalaXpress, rosa geadert, 100g Pulver
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+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

Lieu, date / *Place, date*

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

Nom et fonction / *Name and function*

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*	PalaXpress
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 ++J0141209DEBM0699fAW
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 PalaXpress, verzija 03 *Further Applied standards see Technical Documentation of Product PalaXpress, 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*	04.01.2023
Hanau, 23.12.2024 Mjesto, datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Ime i funkcija / *Name and function*

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*	PalaXpress
Broj verzije / *Version number*	02
Zamjenjuje Dodatak od / *Replaces Annex from*	04.01.2023
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***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
+J014647105160	64710516	PalaXpress, rosa geadert, 1000g Pulver
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+J014647116300	64711630	PalaXpress, rosa, 100g Pulver
+J014647116310	64711631	PalaXpress, 80ml DE/IT
+J014647116930	64711693	PalaXpress, farblos, 100g Pulver
+J014647122450	64712245	PalaXpress, life pink, 1000g
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+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

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*	PalaXpress
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 ++J0141209DEBM0699fAW
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 PalaXpress, Versione 03 *Further Applied standards see Technical Documentation of Product PalaXpress, 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*	04.01.2023
Hanau, 23.12.2024 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.*

KULZER
MITSUI CHEMICALS GROUP

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

Il dispositivo medico / *The medical device*	PalaXpress
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***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
+J014647105160	64710516	PalaXpress, rosa geadert, 1000g Pulver
+J014647113980	64711398	PalaXpress, R50 geadert, 1000g Pulver
+J014647114850	64711485	PalaXpress, farblos, 1000g Pulver
+J014647116300	64711630	PalaXpress, rosa, 100g Pulver
+J014647116310	64711631	PalaXpress, 80ml DE/IT
+J014647116930	64711693	PalaXpress, farblos, 100g Pulver
+J014647122450	64712245	PalaXpress, life pink, 1000g
+J014647124320	64712432	PalaXpress, rosa, 12000g Pulver
+J014647127630	64712763	PalaXpress, rosa opak, 100g Pulver
+J014647127640	64712764	PalaXpress, rosa opak, 1000g Pulver
+J014647149910	64714991	PalaXpress, rosa geadert, 100g Pulver
+J014647149920	64714992	PalaXpress, R50 geadert, 100g Pulver
+J014660201110	66020111	PalaXpress, pink live, 1000g Pulver
+J014660201120	66020112	PalaXpress, pink live, 100g Pulver
+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

Luogo, data / *Place, date*

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

Nome e funzione / *Name and function*

ATITIKTIES DEKLARACIJA / *DECLARATION OF CONFORMITY*

Bendrovės pavadinimas ir adresas / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Vokietija / *Germany* *SRN: DE-MF-000007705*

Prisiimdami visą atsakomybę pareiškiame, kad / *We declare under our sole responsibility that*

medicinos prietaisas / *the medical device*	**PalaXpress**
Pavadinimas, tipas arba modelis, partija arba serijos numeris, galimi šaltiniai ir elementų skaičius / *Name, type or model, batch or serial number, possibly sources and number of items*	Prekių sąrašo ieškokite Priede / *List of Articles see Annex*
EMDN kodas / *EMDN-Code* GMDN kodas / *GMDN code* UMDNS kodas / *UMDNS code* Pagrindinis UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699fAW
klasės / *of class*	IIa
pagal taisyklę / *according to rule*	5-3, 19-3 Pagal Medicinos prietaisų reglamento 2017/745 VIII priedą / *according to Annex VIII of Medical Device Regulation 2017/745*

atitinka visas jam taikomas Medicinos prietaisų reglamento 2017/745 sąlygas. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Taikomi harmonizuotieji standartai, nacionaliniai standartai ar kiti normatyviniai dokumentai / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers atkuriamosiomis medžiagomis Kitus taikomus standartus žr. produkto PalaXpress, techninėje dokumentacijoje, 03 versijoje *Further Applied standards see Technical Documentation of Product PalaXpress, Version 03*
]Atitikties patvirtinimo procedūra pagal / *Conformity assessment procedure acc. to*	Medicinos priemonių reglamento 2017/745 IX priedas, I skyrius, 2 ir 3 straipsniai bei III skyrius *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikuotoji įstaiga / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Vokietija CE 0197
Registracijos numeris / *Registration number:*	HZ 1198082-1
Versijos numeris / *Version number*	03
Pakeičia atitikties deklaraciją nuo / *Replaces Declaration of Conformity from*	04.01.2023
Hanau, 23.12.2024 Vieta, data / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Vardas, pavardė ir pareigos / *Name and function*

Ši atitikties deklaracija galioja 2 metus kartu su atitinkamos pagamintų priemonių partijos pateikimo į rinką dokumentais. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Prekių sąrašas / *List of Articles*
Priedas / *Annex*: Atitikties deklaracija / *Declaration of Conformity*

Medicinos prietaisas / *The medical device*	PalaXpress
Versijos numeris / *Version number*	02
Pakeičia Priedą nuo / *Replaces Annex from*	04.01.2023
Šis straipsnių sąrašas tinka atitikties deklaracijai, kurios versija yra / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Prekės numeris / *Article number***	**Pavadinimas / *Name***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
+J014647105160	64710516	PalaXpress, rosa geadert, 1000g Pulver
+J014647113980	64711398	PalaXpress, R50 geadert, 1000g Pulver
+J014647114850	64711485	PalaXpress, farblos, 1000g Pulver
+J014647116300	64711630	PalaXpress, rosa, 100g Pulver
+J014647116310	64711631	PalaXpress, 80ml DE/IT
+J014647116930	64711693	PalaXpress, farblos, 100g Pulver
+J014647122450	64712245	PalaXpress, life pink, 1000g
+J014647124320	64712432	PalaXpress, rosa, 12000g Pulver
+J014647127630	64712763	PalaXpress, rosa opak, 100g Pulver
+J014647127640	64712764	PalaXpress, rosa opak, 1000g Pulver
+J014647149910	64714991	PalaXpress, rosa geadert, 100g Pulver
+J014647149920	64714992	PalaXpress, R50 geadert, 100g Pulver
+J014660201110	66020111	PalaXpress, pink live, 1000g Pulver
+J014660201120	66020112	PalaXpress, pink live, 100g Pulver
+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

Vieta, data / *Place, date*

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

Vardas, pavardė ir pareigos / *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*	PalaXpress
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 ++J0141209DEBM0699fAW
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 PalaXpress, versie 03 *Further Applied standards see Technical Documentation of Product PalaXpress, 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*	04.01.2023
Hanau, 23.12.2024 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.*

KULZER
MITSUI CHEMICALS GROUP

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

Het medisch hulpmiddel / *The medical device*	PalaXpress
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***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
+J014647105160	64710516	PalaXpress, rosa geadert, 1000g Pulver
+J014647113980	64711398	PalaXpress, R50 geadert, 1000g Pulver
+J014647114850	64711485	PalaXpress, farblos, 1000g Pulver
+J014647116300	64711630	PalaXpress, rosa, 100g Pulver
+J014647116310	64711631	PalaXpress, 80ml DE/IT
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+J014647122450	64712245	PalaXpress, life pink, 1000g
+J014647124320	64712432	PalaXpress, rosa, 12000g Pulver
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+J014647127640	64712764	PalaXpress, rosa opak, 1000g Pulver
+J014647149910	64714991	PalaXpress, rosa geadert, 100g Pulver
+J014647149920	64714992	PalaXpress, R50 geadert, 100g Pulver
+J014660201110	66020111	PalaXpress, pink live, 1000g Pulver
+J014660201120	66020112	PalaXpress, pink live, 100g Pulver
+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

Plaats, datum / *Place, date*

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

Naam en functie / *Name and function*

DECLARAÇÃO DE CONFORMIDADE / *DECLARATION OF CONFORMITY*

Nome e morada da empresa / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Alemanha / *Germany* *SRN: DE-MF-000007705*

Declaramos, sob nossa exclusiva responsabilidade, que / *We declare under our sole responsibility that*

o dispositivo médico / *the medical device*	PalaXpress
Nome, tipo ou modelo, número de lote ou de série, possivelmente origem e quantidade de itens / *Name, type or model, batch or serial number, possibly sources and number of items*	Lista de artigos, ver 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 ++J0141209DEBM0699fAW
da classe / *of class*	IIa
em conformidade com o regulamento / *according to rule*	5-3, 19-3 em conformidade com o Anexo VIII do Regulamento 2017/745 relativo aos Dispositivos Médicos / *according to Annex VIII of Medical Device Regulation 2017/745*

cumpre todas as disposições aplicáveis do Regulamento 2017/745 relativo aos Dispositivos Médicos. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Normas harmonizadas aplicadas, normas nacionais ou outros documentos normativos / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers Outras normas aplicadas, ver Documentação técnica do produto PalaXpress, Versão 03 *Further Applied standards see Technical Documentation of Product PalaXpress, Version 03*
Procedimento de avaliação da conformidade de acordo com / *Conformity assessment procedure acc. to*	Anexo IX do Regulamento 2017/745 relativo aos Dispositivos Médicos, Capítulo I, secção 2 e 3 e 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 / Alemanha CE 0197
Número de registo / *Registration number:*	HZ 1198082-1
Número de versão / *Version number*	03
Substitui a Declaração de Conformidade de / *Replaces Declaration of Conformity from*	04.01.2023
Hanau, 23.12.2024 Local, data / *Place, date*	p.p. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nome e função / *Name and function*

A presente declaração de conformidade é válida durante 2 anos em associação aos documentos do respetivo lote de dispositivos produzidos. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Lista de artigos / *List of Articles*
Anexo / *Annex*: Declaração de Conformidade / *Declaration of Conformity*

O dispositivo médico / *The medical device*	PalaXpress
Número de versão / *Version number*	02
Substitui o Anexo de / *Replaces Annex from*	04.01.2023
A presente lista de artigos é válida para a versão da declaração de conformidade / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Número de artigo / *Article number***	**Nome / *Name***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
+J014647105160	64710516	PalaXpress, rosa geadert, 1000g Pulver
+J014647113980	64711398	PalaXpress, R50 geadert, 1000g Pulver
+J014647114850	64711485	PalaXpress, farblos, 1000g Pulver
+J014647116300	64711630	PalaXpress, rosa, 100g Pulver
+J014647116310	64711631	PalaXpress, 80ml DE/IT
+J014647116930	64711693	PalaXpress, farblos, 100g Pulver
+J014647122450	64712245	PalaXpress, life pink, 1000g
+J014647124320	64712432	PalaXpress, rosa, 12000g Pulver
+J014647127630	64712763	PalaXpress, rosa opak, 100g Pulver
+J014647127640	64712764	PalaXpress, rosa opak, 1000g Pulver
+J014647149910	64714991	PalaXpress, rosa geadert, 100g Pulver
+J014647149920	64714992	PalaXpress, R50 geadert, 100g Pulver
+J014660201110	66020111	PalaXpress, pink live, 1000g Pulver
+J014660201120	66020112	PalaXpress, pink live, 100g Pulver
+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

Local, data / *Place, date*

i.V. Matthias Hartmann

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

Nome e função / *Name and function*

FÖRSÄKRAN OM ÖVERENSSTÄMMELSE / *DECLARATION OF CONFORMITY*

Företagets namn och adress / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Tyskland / *Germany* *SRN: DE-MF-000007705*

Vi försäkrar på eget ansvar att / *We declare under our sole responsibility that*

den medicintekniska produkten / *the medical device*	PalaXpress
Namn, typ eller modell, batch eller serienummer, eventuella källor och antal artiklar / *Name, type or model, batch or serial number, possibly sources and number of items*	Se bilaga för lista över artiklar / *List of Articles see Annex*
EMDN-kod / *EMDN-Code* GMDN-kod / *GMDN code* UMDNS-kod / *UMDNS code* Grundläggande UDI-DI / *Basic UDI-DI*	Q010699 16730 16-728 ++J0141209DEBM0699fAW
i klass / *of class*	IIa
enligt paragraf / *according to rule*	5-3, 19-3 enligt bilaga VIII i förordningen om medicintekniska produkter 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

uppfyller kraven i förordningen om medicintekniska produkter 2017/745 som gäller produkten. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Tillämpade harmoniserade standarder, nationella standarder eller andra normerande dokument / *Applied harmonised standards, national standards or other normative documents*	EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers För ytterligare tillämpade standarder, se teknisk dokumentation för produkten PalaXpress, version 03 *Further Applied standards see Technical Documentation of Product PalaXpress, Version 03*
Förfarande för bedömning av överensstämmelse enl. / *Conformity assessment procedure acc. to*	förordning om medicintekniska 2017/745 bilaga IX, kapitel I, avsnitt 2 och 3 och kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Anmält organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Tyskland CE 0197
Registreringsnummer / *Registration number:*	HZ 1198082-1
Versionsnummer / *Version number*	03
Ersätter försäkran om överensstämmelse från / *Replaces Declaration of Conformity from*	04.01.2023

Hanau, 23.12.2024

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

Ort, datum / *Place, date* — Namn och funktion / *Name and function*

Denna försäkran om överensstämmelse är giltig i 2 år tillsammans med dokumenten för frisläppande av respektive tillverkningsserie av medicintekniska produkter. / *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

Lista över artiklar / *List of Articles*
Bilaga / *Annex*: Försäkran om överensstämmelse / *Declaration of Conformity*

Den medicintekniska produkten / *The medical device*	PalaXpress
Versionsnummer / *Version number*	02
Ersätter bilaga från / *Replaces Annex from*	04.01.2023
Denna artikellista gäller för förklaring av överensstämmelse version / *This article list is valid for the declaration of conformity version*	03

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Namn / *Name***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
+J014647105160	64710516	PalaXpress, rosa geadert, 1000g Pulver
+J014647113980	64711398	PalaXpress, R50 geadert, 1000g Pulver
+J014647114850	64711485	PalaXpress, farblos, 1000g Pulver
+J014647116300	64711630	PalaXpress, rosa, 100g Pulver
+J014647116310	64711631	PalaXpress, 80ml DE/IT
+J014647116930	64711693	PalaXpress, farblos, 100g Pulver
+J014647122450	64712245	PalaXpress, life pink, 1000g
+J014647124320	64712432	PalaXpress, rosa, 12000g Pulver
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+J014647127640	64712764	PalaXpress, rosa opak, 1000g Pulver
+J014647149910	64714991	PalaXpress, rosa geadert, 100g Pulver
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+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

Ort, datum / *Place, date*

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

Namn och funktion / *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*	PalaXpress
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 ++J0141209DEBM0699fAW
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 03 k produktu PalaXpress *Further Applied standards see Technical Documentation of Product PalaXpress, Version 03*
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, 23.12.2024	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Miesto, dátum / *Place, date*	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*

KULZER
MITSUI CHEMICALS GROUP

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

Zdravotnícka pomôcka / *The medical device*	PalaXpress
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***
+J014647105130	64710513	PalaXpress, 500ml DE/GB/FR/NL
+J014647105150	64710515	PalaXpress, rosa, 1000g Pulver
+J014647105160	64710516	PalaXpress, rosa geadert, 1000g Pulver
+J014647113980	64711398	PalaXpress, R50 geadert, 1000g Pulver
+J014647114850	64711485	PalaXpress, farblos, 1000g Pulver
+J014647116300	64711630	PalaXpress, rosa, 100g Pulver
+J014647116310	64711631	PalaXpress, 80ml DE/IT
+J014647116930	64711693	PalaXpress, farblos, 100g Pulver
+J014647122450	64712245	PalaXpress, life pink, 1000g
+J014647124320	64712432	PalaXpress, rosa, 12000g Pulver
+J014647127630	64712763	PalaXpress, rosa opak, 100g Pulver
+J014647127640	64712764	PalaXpress, rosa opak, 1000g Pulver
+J014647149910	64714991	PalaXpress, rosa geadert, 100g Pulver
+J014647149920	64714992	PalaXpress, R50 geadert, 100g Pulver
+J014660201110	66020111	PalaXpress, pink live, 1000g Pulver
+J014660201120	66020112	PalaXpress, pink live, 100g Pulver
+J014660218420	66021842	PalaXpress, natural pink, 1000g Pulver
+J014660707380	66070738	PalaXpress, 500ml IT/ES/PT/LT
+J014660707450	66070745	PalaXpress, 500ml SE/FI/HR/TR/SK

Hanau, 23.12.2024

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: 7C28071E-284B-42DB-A948-F326AB988BFE
Status: Abgeschlossen
Betreff: Mit Docusign abschließen: PalaXpress DoC_V03 + Annex_V02.pdf
Quellumschlag:
Dokumentenseiten: 22
Signaturen: 22
Zertifikatsseiten: 1
Initialen: 0
Signatur mit Anleitung: Aktiviert
Umschlag-ID-Stempel: Aktiviert
Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien

Umschlagersteller:
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Eintragsverfolgung

Status: Original
20.12.2024 13:55:58
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: 77.12.180.40	Gesendet: 20.12.2024 14:02:58 Eingesehen: 23.12.2024 07:39:31 Signiert: 23.12.2024 07:39:56

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	20.12.2024 14:02:58
Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	23.12.2024 07:39:31
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	23.12.2024 07:39:56
Abgeschlossen	Sicherheitsprüfung ausgeführt	23.12.2024 07:39:56

Zahlungen	Status	Zeitstempel