# KONFORMITÄTSERKLÄRUNG / *DECLARATION OF CONFORMITY*

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

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

| | |
|---|---|
| das Medizinprodukt / *the medical device* | **Palapress vario** |
| 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*<br>GMDN-Nummer / *GMDN code*<br>UMDNS-Nummer / *UMDNS code*<br>Basis-UDI-DI / *Basic UDI-DI* | Q010699<br>16730<br>16-728<br>++J0141209DEBM0699eAU |
| 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*<br>Weitere angewandte Normen siehe Version 2 der Technischen Dokumentation von Product Palapress vario / *Further Applied standards see Technical Documentation of Product Palapress vario, Version 2* |
| Konformitätsbewertungsverfahren nach / *Conformity assessment procedure acc. to* | Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I, Abschnitt 2 und 3 und Kapitel III<br>*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<br>Tillystrasse 2<br>90431 Nürnberg / Germany<br><br>CE 0197 |
| Registrierungsnr. / *Registration No.* | HZ 1198082-1 |
| Versionsnummer / *Version number* | 02 |
| Ersetzt Konformitätserklärung vom / *Replaces Declaration of Conformity from* | 29.03.2022 |
| Hanau, Jan 4, 2023<br><br>Ort, Datum / *Place, date* | i.V.<br>Dr. Matthias Hartmann<br>Head of Global Quality, Regulatory & Scientific Services<br>**Kulzer GmbH**<br>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* | **Palapress vario** |
| 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* | 02 |

| **UDI-DI / *UDI-DI*** | **Artikelnummer / *Article number*** | **Name / *Name*** |
|---|---|---|
| +J014647078630 | 64707863 | Palapress vario, 80 ml DE/IT |
| +J014647078640 | 64707864 | Palapress vario, 500 ml DE/GB/FR/NL |
| +J014660707350 | 66070735 | Palapress vario, 500 ml IT/ES/GR/HR |
| +J014660946700 | 66094670 | Palapress vario, 500 ml PL/RO/SK |
| +J014647078700 | 64707870 | Palapress vario, rosa, 100 g |
| +J014647078730 | 64707873 | Palapress vario, farblos, 100 g |
| +J014647078790 | 64707879 | Palapress vario, rosa, 500 g |
| +J014647078820 | 64707882 | Palapress vario, farblos, 500 g |
| +J014647078890 | 64707889 | Palapress vario, rosa, 1000 g |
| +J014647078900 | 64707890 | Palapress vario, rosa opaque, 1000 g |
| +J014647078910 | 64707891 | Palapress vario, rosa gead., 1000 g |
| +J014647078920 | 64707892 | Palapress vario, farblos, 1000 g |
| +J014647078930 | 64707893 | Palapress vario, R 50 gead., 1000 g |
| +J014647123430 | 64712343 | Palapress vario, shade 200, 1000 g |
| +J014647124300 | 64712430 | Palapress vario, rosa, 12000 g |
| +J014647147960 | 64714796 | Palapress vario, light pink, 1000 g |

Hanau, 29.08.2023

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**<br>Leipziger Straße 2, 63450 Hanau<br>Alemania / *Germany*<br><br>*SRN: DE-MF-000007705* |

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

| | |
|---|---|
| el producto sanitario / *the medical device* | **Palapress vario** |
| 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*<br>Código GMDN / *GMDN code*<br>Código UMDNS / *UMDNS code*<br>UDI-DI básico / *Basic UDI-DI* | Q010699<br>16730<br>16-728<br>++J0141209DEBM0699eAU |
| 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<br>Para otras normas aplicadas consulte la documentación técnica del producto Palapress vario, versión 2<br>*Further Applied standards see Technical Documentation of Product Palapress vario, Version 2* |
| Procedimiento de evaluación de la conformidad de acuerdo con /<br>*Conformity assessment procedure acc. to* | Reglamento sobre productos sanitarios 2017/745 Anexo IX, Capítulo I, Secciones 2 y 3 y Capítulo III<br><br>*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<br>Tillystrasse 2<br>90431 Nürnberg / Alemania<br><br>CE 0197 |
| Número de registro / *Registration number*: | HZ 1198082-1 |
| Número de versión / *Version number* | 02 |
| Sustituye a la declaración de conformidad del / *Replaces Declaration of Conformity from* | 29.03.2022 |
| Hanau, Jan 4, 2023<br><br>Lugar, fecha / *Place, date* | i.V. Dr. Matthias Hartmann<br>Head of Global Quality, Regulatory & Scientific Services<br>**Kulzer GmbH**<br>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* | **Palapress vario** |
| 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* | 02 |

| **UDI-DI / *UDI-DI*** | **Número de artículo / *Article number*** | **Nombre / *Name*** |
|---|---|---|
| +J014647078630 | 64707863 | Palapress vario, 80 ml DE/IT |
| +J014647078640 | 64707864 | Palapress vario, 500 ml DE/GB/FR/NL |
| +J014660707350 | 66070735 | Palapress vario, 500 ml IT/ES/GR/HR |
| +J014660946700 | 66094670 | Palapress vario, 500 ml PL/RO/SK |
| +J014647078700 | 64707870 | Palapress vario, rosa, 100 g |
| +J014647078730 | 64707873 | Palapress vario, farblos, 100 g |
| +J014647078790 | 64707879 | Palapress vario, rosa, 500 g |
| +J014647078820 | 64707882 | Palapress vario, farblos, 500 g |
| +J014647078890 | 64707889 | Palapress vario, rosa, 1000 g |
| +J014647078900 | 64707890 | Palapress vario, rosa opaque, 1000 g |
| +J014647078910 | 64707891 | Palapress vario, rosa gead., 1000 g |
| +J014647078920 | 64707892 | Palapress vario, farblos, 1000 g |
| +J014647078930 | 64707893 | Palapress vario, R 50 gead., 1000 g |
| +J014647123430 | 64712343 | Palapress vario, shade 200, 1000 g |
| +J014647124300 | 64712430 | Palapress vario, rosa, 12000 g |
| +J014647147960 | 64714796 | Palapress vario, light pink, 1000 g |

Hanau, 29.08.2023

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**<br>Leipziger Straße 2, 63450 Hanau<br>Allemagne / *Germany*<br><br>*SRN: DE-MF-000007705* |

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

| | |
|---|---|
| le dispositif médical / *the medical device* | **Palapress vario** |
| 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*<br>Code GMDN / *GMDN code*<br>Code UMDNS / *UMDNS code*<br>UDI-DI de base / *Basic UDI-DI* | Q010699<br>16730<br>16-728<br>++J0141209DEBM0699eAU |
| 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<br>Autres normes appliquées voir Documentation technique du produit Palapress vario, version 2<br>*Further Applied standards see Technical Documentation of Product* Palapress vario*, Version 2* |
| 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<br><br>*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<br>Tillystrasse 2<br>90431 Nürnberg / Allemagne<br><br>CE 0197 |
| Numéro d'enregistrement / *Registration number*: | HZ 1198082-1 |
| Numéro de version / *Version number* | 02 |
| Remplace la Déclaration de conformité de / *Replaces Declaration of Conformity from* | 29.03.2022 |
| Hanau, Jan 4, 2023<br><br>Lieu, date / *Place, date* | i.V. Dr. Matthias Hartmann<br>Head of Global Quality, Regulatory & Scientific Services<br>**Kulzer GmbH**<br>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* | **Palapress vario** |
| 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* | 02 |

| **UDI-DI / *UDI-DI*** | **Numéro de référence / *Article number*** | **Nom / *Name*** |
|---|---|---|
| +J014647078630 | 64707863 | Palapress vario, 80 ml DE/IT |
| +J014647078640 | 64707864 | Palapress vario, 500 ml DE/GB/FR/NL |
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| +J014647078730 | 64707873 | Palapress vario, farblos, 100 g |
| +J014647078790 | 64707879 | Palapress vario, rosa, 500 g |
| +J014647078820 | 64707882 | Palapress vario, farblos, 500 g |
| +J014647078890 | 64707889 | Palapress vario, rosa, 1000 g |
| +J014647078900 | 64707890 | Palapress vario, rosa opaque, 1000 g |
| +J014647078910 | 64707891 | Palapress vario, rosa gead., 1000 g |
| +J014647078920 | 64707892 | Palapress vario, farblos, 1000 g |
| +J014647078930 | 64707893 | Palapress vario, R 50 gead., 1000 g |
| +J014647123430 | 64712343 | Palapress vario, shade 200, 1000 g |
| +J014647124300 | 64712430 | Palapress vario, rosa, 12000 g |
| +J014647147960 | 64714796 | Palapress vario, light pink, 1000 g |

Hanau, 29.08.2023

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**<br>Leipziger Straße 2, 63450 Hanau<br>Γερμανία / *Germany*<br>*SRN: DE-MF-000007705* |

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

| | |
|---|---|
| το ιατροτεχνολογικό προϊόν / *the medical device* | **Palapress vario** |
| 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*<br>Κωδικός GMDN / *GMDN code*<br>Κωδικός UMDNS / *UMDNS code*<br>Βασικό UDI-DI / *Basic UDI-DI* | Q010699<br>16730<br>16-728<br>++J0141209DEBM0699eAU |
| 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<br>Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική τεκμηρίωση του Προϊόντος Palapress vario, έκδοση 2<br>*Further Applied standards see Technical Documentation of Product Palapress vario, Version 2* |
| 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<br>*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<br>Tillystrasse 2<br>90431 Nürnberg / Γερμανία<br>CE 0197 |
| Αριθμός καταχώρησης / *Registration number*: | HZ 1198082-1 |
| Αριθμός έκδοσης / *Version number* | 02 |
| Αντικαθιστά τη δήλωση συμμόρφωσης από / *Replaces Declaration of Conformity from* | 29.03.2022 |
| Hanau, | i.V. Dr. Matthias Hartmann<br>Head of Global Quality, Regulatory & Scientific Services<br>**Kulzer GmbH** |
| Τόπος, ημερομηνία / *Place,* Jan 4, 2023 *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* | **Palapress vario** |
| 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* | 02 |

| **UDI-DI / *UDI-DI*** | **Αριθμός είδους / *Article number*** | **Όνομα / *Name*** |
|---|---|---|
| +J014647078630 | 64707863 | Palapress vario, 80 ml DE/IT |
| +J014647078640 | 64707864 | Palapress vario, 500 ml DE/GB/FR/NL |
| +J014660707350 | 66070735 | Palapress vario, 500 ml IT/ES/GR/HR |
| +J014660946700 | 66094670 | Palapress vario, 500 ml PL/RO/SK |
| +J014647078700 | 64707870 | Palapress vario, rosa, 100 g |
| +J014647078730 | 64707873 | Palapress vario, farblos, 100 g |
| +J014647078790 | 64707879 | Palapress vario, rosa, 500 g |
| +J014647078820 | 64707882 | Palapress vario, farblos, 500 g |
| +J014647078890 | 64707889 | Palapress vario, rosa, 1000 g |
| +J014647078900 | 64707890 | Palapress vario, rosa opaque, 1000 g |
| +J014647078910 | 64707891 | Palapress vario, rosa gead., 1000 g |
| +J014647078920 | 64707892 | Palapress vario, farblos, 1000 g |
| +J014647078930 | 64707893 | Palapress vario, R 50 gead., 1000 g |
| +J014647123430 | 64712343 | Palapress vario, shade 200, 1000 g |
| +J014647124300 | 64712430 | Palapress vario, rosa, 12000 g |
| +J014647147960 | 64714796 | Palapress vario, light pink, 1000 g |

Hanau, 29.08.2023

Τόπος, ημερομηνία / *Place, date*

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

Ονοματεπώνυμο και τίτλος / *Name and function*

# IZJAVA O USKLAĐENOSTI / *DECLARATION OF CONFORMITY*

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

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

| | |
|---|---|
| medicinski proizvod / *the medical device* | **Palapress vario** |
| 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*<br>šifra GMDN / *GMDN code*<br>šifra UMDNS / *UMDNS code*<br>osnovni UDI-DI / *Basic UDI-DI* | Q010699<br>16730<br>16-728<br>++J0141209DEBM0699eAU |
| 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<br>Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod Palapress vario, verzija 2<br>*Further Applied standards see Technical Documentation of Product Palapress vario, Version 2* |
| 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<br>*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<br>Tillystrasse 2<br>90431 Nürnberg / Njemačka<br>CE 0197 |
| Registracijski broj / *Registration number*: | HZ 1198082-1 |
| Broj verzije / *Version number* | 02 |
| Zamjenjuje Izjavu o usklađenosti od / *Replaces Declaration of Conformity from* | 29.03.2022 |
| Hanau, Jan 4, 2023 | i.V. Dr. Matthias Hartmann<br>Head of Global Quality, Regulatory & Scientific Services<br>**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* | **Palapress vario** |
| 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* | 02 |

| **UDI-DI / *UDI-DI*** | **Broj artikla / *Article number*** | **Naziv / *Name*** |
|---|---|---|
| +J014647078630 | 64707863 | Palapress vario, 80 ml DE/IT |
| +J014647078640 | 64707864 | Palapress vario, 500 ml DE/GB/FR/NL |
| +J014660707350 | 66070735 | Palapress vario, 500 ml IT/ES/GR/HR |
| +J014660946700 | 66094670 | Palapress vario, 500 ml PL/RO/SK |
| +J014647078700 | 64707870 | Palapress vario, rosa, 100 g |
| +J014647078730 | 64707873 | Palapress vario, farblos, 100 g |
| +J014647078790 | 64707879 | Palapress vario, rosa, 500 g |
| +J014647078820 | 64707882 | Palapress vario, farblos, 500 g |
| +J014647078890 | 64707889 | Palapress vario, rosa, 1000 g |
| +J014647078900 | 64707890 | Palapress vario, rosa opaque, 1000 g |
| +J014647078910 | 64707891 | Palapress vario, rosa gead., 1000 g |
| +J014647078920 | 64707892 | Palapress vario, farblos, 1000 g |
| +J014647078930 | 64707893 | Palapress vario, R 50 gead., 1000 g |
| +J014647123430 | 64712343 | Palapress vario, shade 200, 1000 g |
| +J014647124300 | 64712430 | Palapress vario, rosa, 12000 g |
| +J014647147960 | 64714796 | Palapress vario, light pink, 1000 g |

Hanau, 29.08.2023

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**<br>Leipziger Straße 2, 63450 Hanau<br>Germania / *Germany*<br><br>*SRN: DE-MF-000007705* |

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

| | |
|---|---|
| il dispositivo medico / *the medical device* | **Palapress vario** |
| 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*<br>Codice GMDN / *GMDN code*<br>Codice UMDNS / *UMDNS code*<br>UDI-DI di base / *Basic UDI-DI* | Q010699<br>16730<br>16-728<br>++J0141209DEBM0699eAU |
| 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<br>Ulteriori norme applicate vedi Documentazione tecnica di Prodotto Palapress vario, Versione 2<br>*Further Applied standards see Technical Documentation of Product* Palapress vario*, Version 2* |
| 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<br><br>*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<br>Tillystrasse 2<br>90431 Norimberga / Germania<br><br>CE 0197 |
| Numero di registrazione / *Registration number*: | HZ 1198082-1 |
| Numero versione / *Version number* | 02 |
| Sostituisce la dichiarazione di conformità di / *Replaces Declaration of Conformity from* | 29.03.2022 |
| Hanau, Jan 4, 2023 | i.V. Dr. Matthias Hartmann<br>Head of Global Quality, Regulatory & Scientific Services<br>**Kulzer GmbH** |
| Luogo, data / *Place, date* | Nome e funzione / *Name and function* |

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

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

| | |
|---|---|
| Il dispositivo medico / *The medical device* | **Palapress vario** |
| 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* | 02 |

| **UDI-DI / *UDI-DI*** | **Numero articolo / *Article number*** | **Nome / *Name*** |
|---|---|---|
| +J014647078630 | 64707863 | Palapress vario, 80 ml DE/IT |
| +J014647078640 | 64707864 | Palapress vario, 500 ml DE/GB/FR/NL |
| +J014660707350 | 66070735 | Palapress vario, 500 ml IT/ES/GR/HR |
| +J014660946700 | 66094670 | Palapress vario, 500 ml PL/RO/SK |
| +J014647078700 | 64707870 | Palapress vario, rosa, 100 g |
| +J014647078730 | 64707873 | Palapress vario, farblos, 100 g |
| +J014647078790 | 64707879 | Palapress vario, rosa, 500 g |
| +J014647078820 | 64707882 | Palapress vario, farblos, 500 g |
| +J014647078890 | 64707889 | Palapress vario, rosa, 1000 g |
| +J014647078900 | 64707890 | Palapress vario, rosa opaque, 1000 g |
| +J014647078910 | 64707891 | Palapress vario, rosa gead., 1000 g |
| +J014647078920 | 64707892 | Palapress vario, farblos, 1000 g |
| +J014647078930 | 64707893 | Palapress vario, R 50 gead., 1000 g |
| +J014647123430 | 64712343 | Palapress vario, shade 200, 1000 g |
| +J014647124300 | 64712430 | Palapress vario, rosa, 12000 g |
| +J014647147960 | 64714796 | Palapress vario, light pink, 1000 g |

Hanau, 29.08.2023

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**<br>Leipziger Straße 2, 63450 Hanau<br>Duitsland / *Germany*<br>*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* | **Palapress vario** |
| 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*<br>GMDN-code / *GMDN code*<br>UMDNS-code / *UMDNS code*<br>Basis UDI-DI / *Basic UDI-DI* | Q010699<br>16730<br>16-728<br>++J0141209DEBM0699eAU |
| 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<br>Voor overige toegepaste normen, zie technische documenten van product Palapress vario, versie 2<br>*Further Applied standards see Technical Documentation of Product Palapress vario, Version 2* |
| 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<br>*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<br>Tillystrasse 2<br>90431 Nürnberg / Duitsland<br>CE 0197 |
| Registratienummer / *Registration number*: | HZ 1198082-1 |
| Versienummer / *Version number* | 02 |
| Vervangt de verklaring van conformiteit van / *Replaces Declaration of Conformity from* | 29.03.2022 |
| Hanau, 11.04.2023<br>Plaats, datum / *Place, date* | i.V. Dr. Matthias Hartmann<br>Head of Global Quality, Regulatory & Scientific Services<br>**Kulzer GmbH**<br>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* | **Palapress vario** |
| 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* | 02 |

| **Unieke identificatiecode / *UDI-DI*** | **Artikelnummer / *Article number*** | **Naam / *Name*** |
|---|---|---|
| +J014647078630 | 64707863 | Palapress vario, 80 ml DE/IT |
| +J014647078640 | 64707864 | Palapress vario, 500 ml DE/GB/FR/NL |
| +J014660707350 | 66070735 | Palapress vario, 500 ml IT/ES/GR/HR |
| +J014660946700 | 66094670 | Palapress vario, 500 ml PL/RO/SK |
| +J014647078700 | 64707870 | Palapress vario, rosa, 100 g |
| +J014647078730 | 64707873 | Palapress vario, farblos, 100 g |
| +J014647078790 | 64707879 | Palapress vario, rosa, 500 g |
| +J014647078820 | 64707882 | Palapress vario, farblos, 500 g |
| +J014647078890 | 64707889 | Palapress vario, rosa, 1000 g |
| +J014647078900 | 64707890 | Palapress vario, rosa opaque, 1000 g |
| +J014647078910 | 64707891 | Palapress vario, rosa gead., 1000 g |
| +J014647078920 | 64707892 | Palapress vario, farblos, 1000 g |
| +J014647078930 | 64707893 | Palapress vario, R 50 gead., 1000 g |
| +J014647123430 | 64712343 | Palapress vario, shade 200, 1000 g |
| +J014647124300 | 64712430 | Palapress vario, rosa, 12000 g |
| +J014647147960 | 64714796 | Palapress vario, light pink, 1000 g |

Hanau, 29.08.2023

Plaats, datum / *Place, date*

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

Naam en functie / *Name and function*

# DEKLARACJA ZGODNOŚCI / *DECLARATION OF CONFORMITY*

| | |
|---|---|
| Nazwa i adres firmy / *Name and address of the company* | **Kulzer GmbH**<br>Leipziger Straße 2, 63450 Hanau<br>Niemcy / *Germany*<br><br>*SRN: DE-MF-000007705* |

**Niniejszym deklarujemy pod rygorem odpowiedzialności, że / *We declare under our sole responsibility that***

| | |
|---|---|
| wyrób medyczny / *the medical device* | **Palapress vario** |
| Nazwa, typ lub model, numer partii lub serii, ewentualnie źródła i liczba elementów / *Name, type or model, batch or serial number, possibly sources and number of items* | Wykaz wyrobów znajduje się w załączniku / *List of Articles see Annex* |
| Kod wyrobu wg EMDN / *EMDN-Code*<br>Kod wyrobu wg GMDN / *GMDN code*<br>Kod wyrobu wg UMDNS / *UMDNS code*<br>Kod Basic UDI-DI / *Basic UDI-DI* | Q010699<br>16730<br>16-728<br>++J0141209DEBM0699eAU |
| klasy / *of class* | IIa |
| zgodnie z regułą / *according to rule* | 5-3, 19-3 zgodnie z załącznikiem VIII do Rozporządzenia 2017/745 w sprawie wyrobów medycznych / *according to Annex VIII of Medical Device Regulation 2017/745* |

**spełnia wszystkie przepisy Rozporządzenia 2017/745 w sprawie wyrobów medycznych, które go dotyczą. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***

| | |
|---|---|
| Zastosowane normy zharmonizowane, normy krajowe lub inne dokumenty normatywne / *Applied harmonised standards, national standards or other normative documents* | EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers<br>Pozostałe stosowane normy znajdują się w dokumentacji technicznej produktu Palapress vario, wersja 2<br>*Further Applied standards see Technical Documentation of Product Palapress vario, Version 2* |
| Procedura oceny zgodności wg. / *Conformity assessment procedure acc. to* | Rozporządzenie 2017/745 w sprawie wyrobów medycznych, załącznik IX, rozdział I, sekcja 2 i 3 oraz rozdział III<br><br>*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III* |
| Jednostka notyfikowana / *Notified Body* | TÜV Rheinland LGA Products GmbH<br>Tillystrasse 2<br>90431 Nürnberg/Niemcy<br><br>CE 0197 |
| Numer rejestracyjny / *Registration number*: | HZ 1198082-1 |
| Numer wersji / *Version number* | 02 |
| Zastępuje Deklarację zgodności z / *Replaces Declaration of Conformity from* | 29.03.2022 |
| Hanau, Jan 4, 2023 | i.V. Dr. Matthias Hartmann<br>Head of Global Quality, Regulatory & Scientific Services<br>**Kulzer GmbH** |
| Miejscowość, data / *Place, date* | Imię i nazwisko, stanowisko / *Name and function* |

Niniejsze deklaracja zgodności jest ważna przez 2 lata w połączeniu z dokumentami zwolnienia odpowiedniej partii wyprodukowanych wyrobów. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

# Wykaz wyrobów / *List of Articles*
# Załącznik / *Annex*: Deklaracja zgodności / *Declaration of Conformity*

| | |
|---|---|
| Wyrób medyczny / *The medical device* | **Palapress vario** |
| Numer wersji / *Version number* | 02 |
| Zastępuje załącznik z dnia / *Replaces Annex from* | 04.01.2023 |
| Poniższa lista artykułów obowiązuje dla następujących wersji deklaracji zgodności / *This article list is valid for the declaration of conformity version* | 02 |

| **UDI-DI / *UDI-DI*** | **Numer wyrobu / *Article number*** | **Nazwa / *Name*** |
|---|---|---|
| +J014647078630 | 64707863 | Palapress vario, 80 ml DE/IT |
| +J014647078640 | 64707864 | Palapress vario, 500 ml DE/GB/FR/NL |
| +J014660707350 | 66070735 | Palapress vario, 500 ml IT/ES/GR/HR |
| +J014660946700 | 66094670 | Palapress vario, 500 ml PL/RO/SK |
| +J014647078700 | 64707870 | Palapress vario, rosa, 100 g |
| +J014647078730 | 64707873 | Palapress vario, farblos, 100 g |
| +J014647078790 | 64707879 | Palapress vario, rosa, 500 g |
| +J014647078820 | 64707882 | Palapress vario, farblos, 500 g |
| +J014647078890 | 64707889 | Palapress vario, rosa, 1000 g |
| +J014647078900 | 64707890 | Palapress vario, rosa opaque, 1000 g |
| +J014647078910 | 64707891 | Palapress vario, rosa gead., 1000 g |
| +J014647078920 | 64707892 | Palapress vario, farblos, 1000 g |
| +J014647078930 | 64707893 | Palapress vario, R 50 gead., 1000 g |
| +J014647123430 | 64712343 | Palapress vario, shade 200, 1000 g |
| +J014647124300 | 64712430 | Palapress vario, rosa, 12000 g |
| +J014647147960 | 64714796 | Palapress vario, light pink, 1000 g |

Hanau, 29.08.2023

Miejscowość, data / *Place, date*

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

Imię i nazwisko, stanowisko / *Name and function*

KULZER
MITSUI CHEMICALS GROUP

# DECLARAȚIE DE CONFORMITATE / *DECLARATION OF CONFORMITY*

| | |
|---|---|
| Numele și adresa companiei / *Name and address of the company* | **Kulzer GmbH**<br>Leipziger Straße 2, 63450 Hanau<br>Germania / *Germany*<br><br>*SRN: DE-MF-000007705* |

**Declarăm pe propria răspundere că / *We declare under our sole responsibility that***

| | |
|---|---|
| dispozitivul medical / *the medical device* | **Palapress vario** |
| Nume, tip sau model, număr de lot sau de serie, eventual sursele și numărul de articole / *Name, type or model, batch or serial number, possibly sources and number of items* | Lista de articole, vezi Anexa / *List of Articles see Annex* |
| Cod EMDN / *EMDN-Code*<br>Cod GMDN / *GMDN code*<br>Cod UMDNS / *UMDNS code*<br>UDI-DI de bază / *Basic UDI-DI* | Q010699<br>16730<br>16-728<br>++J0141209DEBM0699eAU |
| din clasa / *of class* | IIa |
| în conformitate cu regula / *according to rule* | 5-3, 19-3 conform Anexei VIII la Regulamentul privind dispozitivele medicale 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745* |

**respectă toate prevederile Regulamentului privind dispozitivele medicale 2017/745 corespunzător. /**
***meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***

| | |
|---|---|
| Standarde armonizate, naționale aplicate sau alte documente normative / *Applied harmonised standards, national standards or other normative documents* | EN ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers<br>Alte standarde aplicate, vezi documentația tehnică a Produsului Palapress vario, Versiunea 2<br>*Further Applied standards see Technical Documentation of Product Palapress vario, Version 2* |
| Procedură de evaluare a conformității în conf. cu / *Conformity assessment procedure acc. to* | Regulamentul privind dispozitivele medicale 2017/745, Anexa IX, Capitolul I, Secțiunile 2 și 3, și Capitolul III<br><br>*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III* |
| Organism notificat / *Notified Body* | TÜV Rheinland LGA Products GmbH<br>Tillystrasse 2<br>90431 Nürnberg / Germania<br><br>CE 0197 |
| Numărul de înregistrare / *Registration number*: | HZ 1198082-1 |
| Număr versiune / *Version number* | 02 |
| Înlocuiește Declarația de conformitate din / *Replaces Declaration of Conformity from* | 29.03.2022 |
| Hanau, Jan 4, 2023<br><br>Loc, dată / *Place, date* | i.V. Dr. Matthias Hartmann<br>Head of Global Quality, Regulatory & Scientific Services<br>**Kulzer GmbH**<br>Nume și funcție / *Name and function* |

Prezenta declarație de conformitate este valabilă timp de 2 ani împreună cu documentele de autorizare pentru respectivul lot de dispozitive produse. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

# Listă de articole / *List of Articles*
# Anexă / *Annex*: Declarație de conformitate / *Declaration of Conformity*

| | |
|---|---|
| Dispozitivul medical / *The medical device* | **Palapress vario** |
| Număr versiune / *Version number* | 02 |
| Înlocuiește Anexa de la / *Replaces Annex from* | 04.01.2023 |
| Această listă de articole este valabilă pentru declarația de conformitate versiunea / *This article list is valid for the declaration of conformity version* | 02 |

| **UDI-DI / *UDI-DI*** | **Număr articol / *Article number*** | **Nume / *Name*** |
|---|---|---|
| +J014647078630 | 64707863 | Palapress vario, 80 ml DE/IT |
| +J014647078640 | 64707864 | Palapress vario, 500 ml DE/GB/FR/NL |
| +J014660707350 | 66070735 | Palapress vario, 500 ml IT/ES/GR/HR |
| +J014660946700 | 66094670 | Palapress vario, 500 ml PL/RO/SK |
| +J014647078700 | 64707870 | Palapress vario, rosa, 100 g |
| +J014647078730 | 64707873 | Palapress vario, farblos, 100 g |
| +J014647078790 | 64707879 | Palapress vario, rosa, 500 g |
| +J014647078820 | 64707882 | Palapress vario, farblos, 500 g |
| +J014647078890 | 64707889 | Palapress vario, rosa, 1000 g |
| +J014647078900 | 64707890 | Palapress vario, rosa opaque, 1000 g |
| +J014647078910 | 64707891 | Palapress vario, rosa gead., 1000 g |
| +J014647078920 | 64707892 | Palapress vario, farblos, 1000 g |
| +J014647078930 | 64707893 | Palapress vario, R 50 gead., 1000 g |
| +J014647123430 | 64712343 | Palapress vario, shade 200, 1000 g |
| +J014647124300 | 64712430 | Palapress vario, rosa, 12000 g |
| +J014647147960 | 64714796 | Palapress vario, light pink, 1000 g |

Hanau, 29.08.2023

Loc, dată / *Place, date*

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

Nume și funcție / *Name and function*

# VYHLÁSENIE O ZHODE / *DECLARATION OF CONFORMITY*

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

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

| | |
|---|---|
| zdravotnícka pomôcka / *the medical device* | **Palapress vario** |
| 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*<br>Kód GMDN / *GMDN code*<br>Kód UMDNS / *UMDNS code*<br>Základné identifikačné číslo UDI-DI / *Basic UDI-DI* | Q010699<br>16730<br>16-728<br>++J0141209DEBM0699eAU |
| 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<br>Ďalšie použité normy nájdete v technickej dokumentácii verzie 2 k produktu Palapress vario<br>*Further Applied standards see Technical Documentation of Product Palapress vario, Version 2* |
| 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<br><br>*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<br>Tillystrasse 2<br>90431 Nürnberg / Nemecko<br><br>CE 0197 |
| Registračné číslo / *Registration number*: | HZ 1198082-1 |
| Číslo verzie / *Version number* | 02 |
| Nahrádza vyhlásenie o zhode z / *Replaces Declaration of Conformity from* | 29.03.2022 |
| Hanau, Jan 4, 2023 | i.V. Dr. Matthias Hartmann<br>Head of Global Quality, Regulatory & Scientific Services<br>**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.*

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

| | |
|---|---|
| Zdravotnícka pomôcka / *The medical device* | **Palapress vario** |
| 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* | 02 |

| **UDI-DI / *UDI-DI*** | **Číslo položky / *Article number*** | **Meno / *Name*** |
|---|---|---|
| +J014647078630 | 64707863 | Palapress vario, 80 ml DE/IT |
| +J014647078640 | 64707864 | Palapress vario, 500 ml DE/GB/FR/NL |
| +J014660707350 | 66070735 | Palapress vario, 500 ml IT/ES/GR/HR |
| +J014660946700 | 66094670 | Palapress vario, 500 ml PL/RO/SK |
| +J014647078700 | 64707870 | Palapress vario, rosa, 100 g |
| +J014647078730 | 64707873 | Palapress vario, farblos, 100 g |
| +J014647078790 | 64707879 | Palapress vario, rosa, 500 g |
| +J014647078820 | 64707882 | Palapress vario, farblos, 500 g |
| +J014647078890 | 64707889 | Palapress vario, rosa, 1000 g |
| +J014647078900 | 64707890 | Palapress vario, rosa opaque, 1000 g |
| +J014647078910 | 64707891 | Palapress vario, rosa gead., 1000 g |
| +J014647078920 | 64707892 | Palapress vario, farblos, 1000 g |
| +J014647078930 | 64707893 | Palapress vario, R 50 gead., 1000 g |
| +J014647123430 | 64712343 | Palapress vario, shade 200, 1000 g |
| +J014647124300 | 64712430 | Palapress vario, rosa, 12000 g |
| +J014647147960 | 64714796 | Palapress vario, light pink, 1000 g |

Hanau, 29.08.2023

Miesto, dátum / *Place, date*

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

Meno a funkcia / *Name and function*