KULZER
MITSUI CHEMICALS GROUP

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*	**Activator Universal Plus** **Optosil** **Xantopren**
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*	Q010201 35866 16-679 ++J0141209IMC0201pVL
der Klasse / *of class*	IIa
nach Regel / *according to rule*	5-1, 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 4823 Zahnheilkunde – Elastomere Abform- und Bissregistriermaterialien / *Dentistry – Elastomeric impression and bite registration materials* Weitere angewandte Normen siehe Version 01 der Technischen Dokumentation von C-Silikone - Activator Universal Plus, Optosil. Oxasil, Xantopren / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren Version 01*
Konformitätsbewertungsverfahren nach / *Conformity assessment procedure acc. to*	Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I, Abschnitt 2 und 3 and 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*	01
Ersetzt Konformitätserklärung vom / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Ort, Datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Name und Funktion / *Name and function*

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*	**Activator Universal Plus** **Optosil** **Xantopren**
Versionsnummer Artikelliste/ *Version number article list*	01
Ersetzt Artikelliste vom / *Replaces article list from*	N/A
Diese Artikelliste ist gültig für die Konformitätserklärung Version/ *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

Ort, Datum / *Place, date*

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

Name und Funktion / *Name and function*

OVERENSSTEMMELSESERKLÆRING / *DECLARATION OF CONFORMITY*

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

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

det medicinske udstyr / *the medical device*	**Activator Universal Plus** **Optosil** **Xantopren**
Betegnelse, type eller model, batch- eller serienummer samt eventuelt oprindelse og antal emner / *Name, type or model, batch or serial number, possibly sources and number of items*	Produktlisten kan ses i bilaget / *List of Articles see Annex*
EMDN-kode / *EMDN-Code* GMDN-kode / *GMDN code* UMDNS-kode / *UMDNS code* Grundlæggende UDI-DI / *Basic UDI-DI*	Q010201 35866 16-679 ++J0141209IMC0201pVL]
i klasse / *of class*	IIa
i henhold til artikel / *according to rule*	5-1, 19-3 i bilag VIII i Europa-Parlamentets og Rådets forordning (EU) 2017/745 om medicinsk udstyr / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Anvendte harmoniserede standarder, nationale standarder eller andre normative dokumenter / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 *Dentistry – Elastomeric impression and bite registration materials* Andre anvendte standarder kan ses i det tekniske dokumentationsmateriale til produktet C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, version 01 / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 01*
Overensstemmelsesvurderingsprocedure iht. / *Conformity assessment procedure acc. to*	Forordning (EU) 2017/745 om medicinsk udstyr, bilag IX, kapitel I, afsnit 2 og 3 samt kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Underrettet organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 D-90431 Nürnberg, Tyskland CE 0197
Registreringsnummer / *Registration number*:	HZ 1198082-1
Versionsnummer / *Version number*	01
Erstatter overensstemmelseserklæring fra / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023	på vegne af Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Sted, dato / *Place, date*	Navn og stilling / *Name and function*

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

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

Det medicinske udstyr / *The medical device*	**Activator Universal Plus** **Optosil** **Xantopren**
Versionsnummer / *Version number*	01
Erstatter bilag fra / *Replaces Annex from*	N/A
Denne artikelliste er gyldig i forbindelse med overensstemmelseserklæringen version / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

Sted, dato / *Place, date*

i.V. Matthias Hartmann

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

Navn og stilling / *Name and function*

DECLARACIÓN DE CONFORMIDAD / *DECLARATION OF CONFORMITY*

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

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

el producto sanitario / *the medical device*	**Activator Universal Plus** **Optosil** **Xantopren**
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*	Q010201 35866 16-679 ++J0141209IMC0201pVL
de la clase / *of class*	IIa
de acuerdo con la norma / *according to rule*	5-1, 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 4823 *Dentistry – Elastomeric impression and bite registration materials* Para otras normas aplicadas consulte la documentación técnica del producto C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, versión 01 *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 01*
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*	01
Sustituye a la declaración de conformidad del / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Lugar, fecha / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nombre y cargo / *Name and function*

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*	**Activator Universal Plus** **Optosil** **Xantopren**
Número de versión / *Version number*	01
Sustituye al Anexo del / *Replaces Annex from*	N/A
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*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

Lugar, fecha / *Place, date*

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

Nombre y cargo / *Name and function*

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*	**Activator Universal Plus** **Optosil** **Xantopren**
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*	Q010201 35866 16-679 ++J0141209IMC0201pVL
luokka / *of class*	IIa
säädös / *according to rule*	5-1, 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 4823 *Dentistry – Elastomeric impression and bite registration materials* Muut sovellettavat standardit, ks. tekniset tiedot tuotteesta C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren versio 01 / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 01*
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*	01
Korvaa vaatimustenmukaisuusvakuutuksen / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Paikka, päiväys / *Place, date*	i.V Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** 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*	**Activator Universal Plus** **Optosil** **Xantopren**
Versionumero / *Version number*	01
Korvaa liitteen / *Replaces Annex from*	N/A
Tämä artikkeliluettelo pätee vaatimustenmukaisuusvakuutuksen versioon / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

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*	**Activator Universal Plus** **Optosil** **Xantopren**
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*	Q010201 35866 16-679 ++J0141209IMC0201pVL
de classe / *of class*	IIa
selon la règle / *according to rule*	5-1, 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 4823 *Dentistry – Elastomeric impression and bite registration materials* Autres normes appliquées voir Documentation technique du produit C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, version 01 / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 01*
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*	01
Remplace la Déclaration de conformité de / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Lieu, date / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nom et fonction / *Name and function*

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*	**Activator Universal Plus** **Optosil** **Xantopren**
Numéro de version / *Version number*	01
Remplace l'annexe de / *Replaces Annex from*	N/A
Cette liste d'articles est valable pour la déclaration de conformité, version / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

Lieu, date / *Place, date*

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

Nom et fonction / *Name and function*

DEARBHÚ COMHRÉIREACHTA / *DECLARATION OF CONFORMITY*

Ainm agus seoladh na cuideachta / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau An Ghearmáin / *Germany* *SRN: DE-MF-000007705*

Dearbhaíonn muid faoinár gcúram aonair go bhfuil / *We declare under our sole responsibility that*

an fheiste leighis / *the medical device*	**Activator Universal Plus** **Optosil** **Xantopren**
Ainm, cineál nó leagan, baisc nó sraithuimhir, b'fhéidir foinsí agus líon earraí / *Name, type or model, batch or serial number, possibly sources and number of items*	Féach Aguisín do Liosta Airteagal /*List of Articles see Annex*
Cód-EMDN / *EMDN-Code* cód GMDN / *GMDN code* cód UMDNS / *UMDNS code* UDI-DI Bunúsach / *Basic UDI-DI*	Q010201 35866 16-679 ++J0141209IMC0201pVL
d'aicme / *of class*	IIa
de réir rialach / *according to rule*	5-1, 19-3 de réir Aguisín VIII de Rialachán Feiste Leighis 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

comhlíonann sé na forálacha uilig sa Rialachán Feiste Leighis 2017/745 atá i bhfeidhm air. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Caighdeáin chomhoiriúnaithe i bhfeidhm, caighdeáin náisiúnta nó cáipéisí normatacha eile / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 *Dentistry – Elastomeric impression and bite registration materials* Féach Cáipéisíocht Theicniúil do Chaighdeáin Bhreise i bhfeidhm ar Táirge C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren,, Leagan 1 / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 1*
Gnáthamh measúnaithe comhréireachta de réir / *Conformity assessment procedure acc. to*	Rialachán Feiste Leighis 2017/745 Iarscríbhinn IX, Caibidil I, Alt 2 agus 3 agus Caibidil III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Comhlacht a dtugtar fógra dó / *Notified Body*	TÜV Rheinland LGA Táirgí GmbH Tillystrasse 2 90431 Nürnberg / An Ghearmáin CE 0197
Uimhir chláraithe / *Registration number*:	HZ 1198082-1
Uimhir leagain / *Version number*	01
Tagann sé in áit Dearbhú Comhréireachta ó / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Láthair, dáta / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Ainm agus feidhm / *Name and function*

Tá an dearbhú comhréireachta seo bailí feadh 2 bhliain i dtaca leis na cáipéisí fuascailte don bhaisc faoi seach de na feistí táirgthe / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Liosta Airteagal / *List of Articles*
Aguisín / *Annex*: Dearbhú Comhréireachta / *Declaration of Conformity*

An fheiste leighis / *The medical device*	**Activator Universal Plus** **Optosil** **Xantopren**
Uimhir leagain / *Version number*	01
Tagann sé in áit Aguisín ó / *Replaces Annex from*	N/A
Tá an liosta airteagail bailí don dearbhú comhréireachta leagan / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Uimhir airteagail / *Article number***	**Ainm / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

Láthair, dáta / *Place, date*

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

Ainm agus feidhm / *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*	**Activator Universal Plus** **Optosil** **Xantopren**
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*	Q010201 35866 16-679 ++J0141209IMC0201pVL
di classe / *of class*	IIa
secondo la norma / *according to rule*	5-1, 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 4823 *Dentistry – Elastomeric impression and bite registration materials* Ulteriori norme applicate vedi Documentazione tecnica di Prodotto C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Versione 01 / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 01*
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*	01
Sostituisce la dichiarazione di conformità di / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Luogo, data / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nome e funzione / *Name and function*

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*	**Activator Universal Plus** **Optosil** **Xantopren**
Numero versione / *Version number*	01
Sostituisce l'allegato da / *Replaces Annex from*	N/A
Questa lista di articoli è valida per la versione della dichiarazione di conformità / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

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** 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*	**Activator Universal Plus** **Optosil** **Xantopren**
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*	Q010201 35866 16-679 ++J0141209IMC0201pVL
van klasse / *of class*	IIa
in overeenstemming met regelgeving / *according to rule*	5-1, 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 4823 *Dentistry – Elastomeric impression and bite registration materials* Voor overige toegepaste normen, zie technische documenten van product C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, versie 01 / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 01*
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*	01
Vervangt de verklaring van conformiteit van / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Plaats, datum / *Place, date*	Naam en functie / *Name and function*

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

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

Het medisch hulpmiddel / *The medical device*	**Activator Universal Plus** **Optosil** **Xantopren**
Versienummer / *Version number*	01
Vervangt de bijlage van / *Replaces Annex from*	N/A
Deze artikellijst is geldig voor de conformiteitsverklaring, versie / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

Plaats, datum / *Place, date*

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

Naam en functie / *Name and function*

SAMSVARSERKLÆRING / *DECLARATION OF CONFORMITY*

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

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

det medisinske utstyret / *the medical device*	**Activator Universal Plus** **Optosil** **Xantopren**
Navn, type eller modell, parti- eller serienummer, eventuelt kilder og antall elementer / *Name, type or model, batch or serial number, possibly sources and number of items*	Liste over artikler, se vedlegg / *List of Articles, see Annex*
EMDN-kode / *EMDN-Code* GMDN-kode / *GMDN code* UMDNS-kode / *UMDNS code* Grunnleggende UDI-DI / *Basic UDI-DI*	Q010201 35866 16-679 ++J0141209IMC0201pVL
i klasse / *of class*	IIa
i henhold til regel / *according to rule*	5-1, 19-3 i henhold til vedlegg VIII i forordning 2017/745 om medisinsk utstyr / *according to Annex VIII of Medical Device Regulation 2017/745*

oppfyller alle relevante bestemmelser i forordning 2017/745 om medisinsk utstyr. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Anvendte harmoniserte standarder, nasjonale standarder eller andre normative dokumenter / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 *Dentistry – Elastomeric impression and bite registration materials* Ytterligere anvendte standarder, se teknisk dokumentasjon for produktet C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, versjon 01 / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 01*
Prosedyre for samsvarsvurdering i henhold til / *Conformity assessment procedure acc. to*	forordning 2017/745 om medisinsk utstyr vedlegg IX, kapittel I, avsnitt 2 og 3 og kapittel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Teknisk kontrollorgan / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Tyskland CE 0197
Registreringsnummer / *Registration number*:	HZ 1198082-1
Versjonsnummer / *Version number*	01
Erstatter samsvarserklæring fra / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Sted, dato / *Place, date*	Navn og funksjon / *Name and function*

Denne samsvarserklæringen er gyldig i 2 år i tilknytning til frigivelsesdokumentene for det aktuelle partiet med produsert utstyr/
This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.

Liste over artikler / *List of Articles*
Vedlegg / *Annex*: Samsvarserklæring / *Declaration of Conformity*

Det medisinske utstyret / *The medical device*	**Activator Universal Plus** **Optosil** **Xantopren**
Versjonsnummer / *Version number*	01
Erstatter vedlegg fra / *Replaces Annex from*	N/A
Denne artikkellisten gjelder for samsvarserklæringsversjon / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

Sted, dato / *Place, date*

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

Navn og funksjon / *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*	**Activator Universal Plus** **Optosil** **Xantopren**
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*	Q010201 35866 16-679 ++J0141209IMC0201pVL
da classe / *of class*	IIa
em conformidade com o regulamento / *according to rule*	5-1, 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 4823 *Dentistry – Elastomeric impression and bite registration materials* Outras normas aplicadas, ver Documentação técnica do produto C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Versão 01 / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 01*
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*	01
Substitui a Declaração de Conformidade de / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 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*

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*	**Activator Universal Plus** **Optosil** **Xantopren**
Número de versão / *Version number*	01
Substitui o Anexo de / *Replaces Annex from*	N/A
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*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

Local, data / *Place, date*

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*	**Activator Universal Plus** **Optosil** **Xantopren**
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*	Q010201 35866 16-679 ++J0141209IMC0201pVL
i klass / *of class*	IIa
enligt paragraf / *according to rule*	5-1, 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 4823 *Dentistry – Elastomeric impression and bite registration materials* För ytterligare tillämpade standarder, se teknisk dokumentation för produkten C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, version 01 / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version* 01
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*	01
Ersätter försäkran om överensstämmelse från / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Ort, datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** 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.*

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

Den medicintekniska produkten / *The medical device*	**Activator Universal Plus** **Optosil** **Xantopren**
Versionsnummer / *Version number*	01
Ersätter bilaga från / *Replaces Annex from*	N/A
Denna artikellista gäller för förklaring av överensstämmelse version / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660374430	66037443	Activator Universal Plus Paste 60mL
+J014660374450	66037445	Activator Universal Plus Liquid 25mL
+J014660374470	66037447	Activator Universal Plus Paste Regional
+J014660456820	66045682	Optosil Comfort 1x450 mL Regional
+J014660795890	66079589	Optosil Comfort 1x900 mL Regional
+J014500342020	50034202	Optosil Comfort 1x900 mL
+J014653828290	65382829	Optosil Comfort 1x6850 mL
+J014660795900	66079590	Optosil P Plus 1x900 mL Regional
+J014656157500	65615750	Optosil P Plus 1x6850 mL
+J014660464750	66046475	Optosil P Plus 1x900 mL
+J014500341020	50034102	Xantopren Comfort Light 1x(2x50 mL)
+J014500341050	50034105	Xantopren Comfort Medium 1x(2x50 mL)
+J014660464760	66046476	Xantopren H Green 1x140 mL
+J014660464480	66046448	Xantopren L Blue 1x140 mL
+J014660795910	66079591	Xantopren L Blue 1x140 mL Regional
+J014660464470	66046447	Xantopren M Mucosa 1x140 mL
+J014660464490	66046449	Xantopren VL Plus 1x140 mL
+J014660795920	66079592	Xantopren VL Plus 1x140 mL Regional

Hanau, 01.11.2023

Ort, datum / *Place, date*

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

Namn och funktion / *Name and function*