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*	**Gluma Desensitizer**
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*	Q010101 34782 10-034 ++J0141103DES010104e5J
der Klasse / *of class*	IIa
nach Regel / *according to rule*	8 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*	Weitere angewandte Normen siehe Version 1 der Technischen Dokumentation von Produkt Gluma Desensitizer / *Further Applied standards see Technical Documentation of Product Gluma Desensitizers, Version 1*
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, Dez 1, 2022	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Ort, Datum / *Place, date*	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*	**Gluma Desensitizer**
Versionsnummer Artikelliste/ *Version number article list*	**V01**
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*	**V01**

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014658723540	65872354	GLUMA DESENSITIZER 1 X 5 ML
+J014660018540	66001854	GLUMA DESENSITIZER SINGLE DOSE 40 X 1 ST
+J014660037640	66003764	GLUMA DESENSITIZER 1 X 5 ML REGIO
+J014660182210	66018221	GLUMA DESENSITIZER VALUE PACK 3 X 5 ML

Hanau, Dez 1, 2022

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*	**Gluma Desensitizer**
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*	Q010101 34782 10-034 ++J0141103DES010104e5J
i klasse / *of class*	IIa
i henhold til artikel / *according to rule*	8 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*	Andre anvendte standarder kan ses i det tekniske dokumentationsmateriale til produktet Gluma Desensitizer, version 1 *Further Applied standards see Technical Documentation of Product* Gluma Desensitizer*, Version 1*
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, Dez 1, 2022 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*

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*	**Gluma Desensitizer**
Versionsnummer / *Version number*	**V01**
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*	**V01**

UDI-DI / *UDI-DI*	**Varenummer / *Article number***	**Betegnelse / *Name***
+J014658723540	65872354	GLUMA DESENSITIZER 1 X 5 ML
+J014660018540	66001854	GLUMA DESENSITIZER SINGLE DOSE 40 X 1 ST
+J014660037640	66003764	GLUMA DESENSITIZER 1 X 5 ML REGIO
+J014660182210	66018221	GLUMA DESENSITIZER VALUE PACK 3 X 5 ML

Hanau, Dez 1, 2022

Sted, dato / *Place, date*

i.V.

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

Navn og stilling / *Name and function*

DECLARACIÓN DE CONFORMIDAD / *DECLARATION OF CONFORMITY*

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

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

el producto sanitario / *the medical device*	**Gluma Desensitizer**
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*	Q010101 34782 10-034 ++J0141103DES010104e5J
de la clase / *of class*	IIa
de acuerdo con la norma / *according to rule*	8 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*	Para otras normas aplicadas consulte la documentación técnica del producto Gluma Desensitizer, versión 1 *Further Applied standards see Technical Documentation of Product* Gluma Desensitizer*, Version 1*
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, Dez 1, 2022 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*	**Gluma Desensitizer**
Número de versión / *Version number*	**V01**
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*	**V01**

UDI-DI / *UDI-DI*	**Número de artículo / *Article number***	**Nombre / *Name***
+J014658723540	65872354	GLUMA DESENSITIZER 1 X 5 ML
+J014660018540	66001854	GLUMA DESENSITIZER SINGLE DOSE 40 X 1 ST
+J014660037640	66003764	GLUMA DESENSITIZER 1 X 5 ML REGIO
+J014660182210	66018221	GLUMA DESENSITIZER VALUE PACK 3 X 5 ML

Hanau, Dez 1, 2022

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*	**Gluma Desensitizer**
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*	Q010101 34782 10-034 ++J0141103DES010104e5J
luokka / *of class*	IIa
säädös / *according to rule*	8 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*	Muut sovellettavat standardit, ks. tekniset tiedot tuotteesta Gluma Desensitizer, versio 1 *Further Applied standards see Technical Documentation of Product* Gluma Desensitizer*, Version 1*
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, Dez 1, 2022 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*	**Gluma Desensitizer**
Versionumero / *Version number*	**V01**
Korvaa liitteen / *Replaces Annex from*	**N/A**
Tämä artikkeliluettelo pätee vaatimustenmukaisuusvakuutuksen versioon / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI / *UDI-DI*	**Artikkelinumero / *Article number***	**Nimi / *Name***
+J014658723540	65872354	GLUMA DESENSITIZER 1 X 5 ML
+J014660018540	66001854	GLUMA DESENSITIZER SINGLE DOSE 40 X 1 ST
+J014660037640	66003764	GLUMA DESENSITIZER 1 X 5 ML REGIO
+J014660182210	66018221	GLUMA DESENSITIZER VALUE PACK 3 X 5 ML

Hanau, Dez 1, 2022

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*	**Gluma Desensitizer**
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*	Q010101 34782 10-034 ++J0141103DES010104e5J
de classe / *of class*	IIa
selon la règle / *according to rule*	8 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*	Autres normes appliquées voir Documentation technique du produit Gluma Desensitizer, version 1 *Further Applied standards see Technical Documentation of Product* Gluma Desensitizer*, Version 1*
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, Dez 1, 2022 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*	**Gluma Desensitizer**
Numéro de version / *Version number*	**V01**
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*	**V01**

UDI-DI / *UDI-DI*	**Numéro de référence / *Article number***	**Nom / *Name***
+J014658723540	65872354	GLUMA DESENSITIZER 1 X 5 ML
+J014660018540	66001854	GLUMA DESENSITIZER SINGLE DOSE 40 X 1 ST
+J014660037640	66003764	GLUMA DESENSITIZER 1 X 5 ML REGIO
+J014660182210	66018221	GLUMA DESENSITIZER VALUE PACK 3 X 5 ML

Hanau, Dez 1, 2022

Lieu, date / *Place, date*

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

Nom et fonction / *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*	**Gluma Desensitizer**
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*	Q010101 34782 10-034 ++J0141103DES010104e5J
di classe / *of class*	IIa
secondo la norma / *according to rule*	8 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*	Ulteriori norme applicate vedi Documentazione tecnica di Prodotto Gluma Desensitizer, Versione 1 *Further Applied standards see Technical Documentation of Product* Gluma Desensitizer*, Version 1*
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, Dez 1, 2022 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*	**Gluma Desensitizer**
Numero versione / *Version number*	**V01**
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*	**V01**

UDI-DI / *UDI-DI*	**Numero articolo / *Article number***	**Nome / *Name***
+J014658723540	65872354	GLUMA DESENSITIZER 1 X 5 ML
+J014660018540	66001854	GLUMA DESENSITIZER SINGLE DOSE 40 X 1 ST
+J014660037640	66003764	GLUMA DESENSITIZER 1 X 5 ML REGIO
+J014660182210	66018221	GLUMA DESENSITIZER VALUE PACK 3 X 5 ML

Hanau, Dez 1, 2022

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*	**Gluma Desensitizer**
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*	Q010101 34782 10-034 ++J0141103DES010104e5J
van klasse / *of class*	IIa
in overeenstemming met regelgeving / *according to rule*	8 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*	Voor overige toegepaste normen, zie technische documenten van product Gluma Desensitizer, versie 1 *Further Applied standards see Technical Documentation of Product* Gluma Desensitizer, *Version 1*
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, Dez 1, 2022 Plaats, datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Naam en functie / *Name and function*

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

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

Het medisch hulpmiddel / *The medical device*	**Gluma Desensitizer**
Versienummer / *Version number*	**V01**
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*	**V01**

Unieke identificatiecode / *UDI-DI*	**Artikelnummer / *Article number***	**Naam / *Name***
+J014658723540	65872354	GLUMA DESENSITIZER 1 X 5 ML
+J014660018540	66001854	GLUMA DESENSITIZER SINGLE DOSE 40 X 1 ST
+J014660037640	66003764	GLUMA DESENSITIZER 1 X 5 ML REGIO
+J014660182210	66018221	GLUMA DESENSITIZER VALUE PACK 3 X 5 ML

Hanau, Dez 1, 2022

Plaats, datum / *Place, date*

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

Naam en functie / *Name and function*

DECLARAÇÃO DE CONFORMIDADE / *DECLARATION OF CONFORMITY*

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

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

o dispositivo médico / *the medical device*	**Gluma Desensitizer**
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*	Q010101 34782 10-034 ++J0141103DES010104e5J
da classe / *of class*	IIa
em conformidade com o regulamento / *according to rule*	8 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*	Outras normas aplicadas, ver Documentação técnica do produto Gluma Desensitizer, Versão 1 *Further Applied standards see Technical Documentation of Product* Gluma Desensitizer*, Version 1*
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, Dez 1, 2022 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*	**Gluma Desensitizer**
Número de versão / *Version number*	**V01**
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*	**V01**

UDI-DI / *UDI-DI*	**Número de artigo / *Article number***	**Nome / *Name***
+J014658723540	65872354	GLUMA DESENSITIZER 1 X 5 ML
+J014660018540	66001854	GLUMA DESENSITIZER SINGLE DOSE 40 X 1 ST
+J014660037640	66003764	GLUMA DESENSITIZER 1 X 5 ML REGIO
+J014660182210	66018221	GLUMA DESENSITIZER VALUE PACK 3 X 5 ML

Hanau, Dez 1, 2022

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*

DECLARAȚIE DE CONFORMITATE / *DECLARATION OF CONFORMITY*

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

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

dispozitivul medical / *the medical device*	**Gluma Desensitizer**
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* Cod GMDN / *GMDN code* Cod UMDNS / *UMDNS code* UDI-DI de bază / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103DES010104e5J
din clasa / *of class*	IIa
în conformitate cu regula / *according to rule*	8 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*	Alte standarde aplicate, vezi documentația tehnică a Produsului Gluma Desensitizer, Versiunea 1 *Further Applied standards see Technical Documentation of Product* Gluma Desensitizer*, Version 1*
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 *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 Tillystrasse 2 90431 Nürnberg / Germania CE 0197
Numărul de înregistrare / *Registration number*:	HZ 1198082-1
Număr versiune / *Version number*	01
Înlocuiește Declarația de conformitate din / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 1, 2022	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Loc, dată / *Place, date*	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*	**Gluma Desensitizer**
Număr versiune / *Version number*	**V01**
Înlocuiește Anexa de la / *Replaces Annex from*	**N/A**
Această listă de articole este valabilă pentru declarația de conformitate versiunea / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI / *UDI-DI*	**Număr articol / *Article number***	**Nume / *Name***
+J014658723540	65872354	GLUMA DESENSITIZER 1 X 5 ML
+J014660018540	66001854	GLUMA DESENSITIZER SINGLE DOSE 40 X 1 ST
+J014660037640	66003764	GLUMA DESENSITIZER 1 X 5 ML REGIO
+J014660182210	66018221	GLUMA DESENSITIZER VALUE PACK 3 X 5 ML

Hanau, Dez 1, 2022

Loc, dată / *Place, date*

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

Nume și funcție / *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*	**Gluma Desensitizer**
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*	Q010101 34782 10-034 ++J0141103DES010104e5J
i klass / *of class*	IIa
enligt paragraf / *according to rule*	8 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*	För ytterligare tillämpade standarder, se teknisk dokumentation för produkten Gluma Desensitizer, version 1 *Further Applied standards see Technical Documentation of Product* Gluma Desensitizer*, Version 1*
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, Dez 1, 2022 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*	**Gluma Desensitizer**
Versionsnummer / *Version number*	**V01**
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*	**V01**

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Namn / *Name***
+J014658723540	65872354	GLUMA DESENSITIZER 1 X 5 ML
+J014660018540	66001854	GLUMA DESENSITIZER SINGLE DOSE 40 X 1 ST
+J014660037640	66003764	GLUMA DESENSITIZER 1 X 5 ML REGIO
+J014660182210	66018221	GLUMA DESENSITIZER VALUE PACK 3 X 5 ML

Hanau, Dez 1, 2022

Ort, datum / *Place, date*

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

Namn och funktion / *Name and function*

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Umschlag-ID: C31A2CF3DEAA4129A8AAA94C66886624
Status: Abgeschlossen
Betreff: Mit DocuSign abschließen: Gluma Desensitizer combined.pdf
Quellumschlag:
Dokumentenseiten: 20
Signaturen: 20
Umschlagersteller:
Zertifikatsseiten: 4
Initialen: 0
Anette Stadtfeld
Signatur mit Anleitung: Aktiviert
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Umschlag-ID-Stempel: Aktiviert
Hanau, Hessen 63450
Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien
Anette.Stadtfeld@kulzer-dental.com
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Unterzeichnerereignisse	Signatur	Zeitstempel
Matthias Hartmann matthias.hartmann@kulzer-dental.com PRRC Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	 Signaturübernahme: Hochgeladenes Signaturbild Mit IP-Adresse: 77.182.20.176	Gesendet: 29.11.2022 11:40:16 Eingesehen: 01.12.2022 07:17:07 Signiert: 01.12.2022 07:17:37

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:
Akzeptiert: 01.12.2022 07:17:07
ID: dadc89ca-49f5-45c8-9176-6b9937094805

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Bearbeiterversandereignisse	Status	Zeitstempel

Beauftragtenzustellereignisse	Status	Zeitstempel

Vermittlerversandereignisse	Status	Zeitstempel

Zertifizierter Versand - Ereignisse	Status	Zeitstempel

Kopienereignisse	Status	Zeitstempel

Zeugen-Ereignisse	Signatur	Zeitstempel

Notarereignisse	Signatur	Zeitstempel

Umschlagereignisse – Überblick	Status	Zeitstempel
Umschlag gesendet	Hash-codiert/verschlüsselt	29.11.2022 11:40:16
Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	01.12.2022 07:17:07
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	01.12.2022 07:17:37
Abgeschlossen	Sicherheitsprüfung ausgeführt	01.12.2022 07:17:37

Zahlungen	Status	Zeitstempel

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