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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 Bond Universal / GLUMA Ceramic Primer**
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 ++J0141103BA01010104cLA
der Klasse / *of class*	IIa
nach Regel / *according to rule*	8-1 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 4049 - Dentistry– Polymer-based restorative materials Weitere angewandte Normen siehe Version 2 der Technischen Dokumentation von Produkt GLUMA Bond Universal / GLUMA Ceramic Primer *Further Applied standards see Technical Documentation of Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, Version 2*
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*	28.03.2022
Hanau, Aug 15, 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*

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.*

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Artikelliste / *List of Articles*
Anhang zur Konformitätserklärung / Annex to declaration of conformity

das Medizinprodukt / *for the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Versionsnummer Artikelliste/ *Version number article list*	**V02**
Ersetzt Artikelliste vom / *Replaces article list from*	**V01, 28.03.2022**
Diese Artikelliste ist gültig für die Konformitätserklärung Version/ *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 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*

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ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ / *DECLARATION OF CONFORMITY*

Име и адрес на фирмата / *Name and address of the company*	*Kulzer GmbH* *Leipziger Straße 2, 63450 Hanau* *Германия / Germany* *SRN: DE-MF-000007705*

Декларираме на наша собствена отговорност, че / *We declare under our sole responsibility that*

медицинското изделие / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Наименование, тип или модел, партиден или сериен номер, евентуално произход и брой елементи / *Name, type or model, batch or serial number, possibly sources and number of items*	Списък с артикули, вижте Приложението / *List of Articles see Annex*
Код по EMDN / *EMDN-Code* Код по GMDN / *GMDN code* Код по UMDNS / *UMDNS code* Основна UDI-DI идентификация / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
от клас / *of class*	IIa
съгласно правило / *according to rule*	8-1 съгласно Приложение VIII от Регламента за медицинските изделия 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

отговаря на всички разпоредби на Регламента за медицинските изделия 2017/745, който се прилага за него. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Приложени хармонизирани стандарти, национални стандарти или други нормативни документи / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Други приложени стандарти, вижте техническата документация на продукт GLUMA Bond Universal / GLUMA Ceramic Primer Версия 2 *Further Applied standards see Technical Documentation of Product [*GLUMA Bond Universal / GLUMA Ceramic Primer*, Version 2*
Процедура за оценка на съответствието съгласно / *Conformity assessment procedure acc. to*	Регламента за медицинските изделия 2017/745 Приложение IX, глава I, раздел 2 и 3 и глава III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Нотифициран орган / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Германия CE 0197
Регистрационен номер / *Registration number*:	HZ 1198082-1
Номер на версия / *Version number*	01
Заменя Декларация за съответствие от / *Replaces Declaration of Conformity from*	28.03.2022
Ханау, Aug 15, 2022 Място, дата / *Place, date*	i.V. от името на д-р Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Име и длъжност / *Name and function*

Тази Декларация за съответствие е валидна за 2 години във връзка с публикуваните документи за съответната партида произведени устройства / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

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Списък с артикули / *List of Articles*
Приложение / *Annex*: Декларация за съответствие / *Declaration of Conformity*

Медицинското изделие / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Номер на версия / *Version number*	**V02**
Заменя Приложението от / *Replaces Annex from*	**V01, 28.03.2022**
Този списък със статии е валиден във връзка с декларацията за съответствие, версия / This This *article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Ханау, Nov 23, 2022

Място, дата / *Place, date*

i.V.

от името на д-р Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Име и длъжност / Name and function

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PROHLÁŠENÍ O SHODĚ / *DECLARATION OF CONFORMITY*

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

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

zdravotnický prostředek / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Název, typ nebo model, šarže nebo výrobní číslo, případně zdroje a počet kusů / *Name, type or model, batch or serial number, possibly sources and number of items*	Seznam položek je uveden v příloze / *List of Articles see Annex*
Kód EMDN / *EMDN-Code* Kód GMDN / *GMDN code* Kód UMDNS / *UMDNS code* Základní UDI-DI / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
třídy / *of class*	IIa
podle pravidla / *according to rule*	8-1 podle přílohy VIII k nařízení 2017/745 o zdravotnických prostředcích / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Použité harmonizované normy, národní normy nebo jiné normativní dokumenty / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Další použité normy najdete v technické dokumentaci k výrobku GLUMA Bond Universal / GLUMA Ceramic Primer, verze 2 *Further Applied standards see Technical Documentation of Product* GLUMA Bond Universal / GLUMA Ceramic Primer, *Version 2*
Procedura posouzení shody podle / *Conformity assessment procedure acc. to*	nařízení 2017/745 o zdravotnických prostředcích, příloha IX, kapitola I, oddíl 2 a 3 a kapitola III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikovaná osoba / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Německo CE 0197
Registrační číslo / *Registration number*:	HZ 1198082-1
Číslo verze / *Version number*	01
Nahrazuje Prohlášení o shodě ze dne / *Replaces Declaration of Conformity from*	28.03.2022
Hanau, Aug 15, 2022	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Místo, datum / *Place, date*	Jméno a funkce / *Name and function*

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

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

Zdravotnický prostředek / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Číslo verze / *Version number*	**V02**
Nahrazuje přílohu ze dne / *Replaces Annex from*	**V01, 28.03.2022**
Tento seznam zboží platí pro verzi prohlášení o shodě / *This article list is valid for the declaration of conformity version:*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 2022

Místo, datum / *Place, date*

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

Jméno a funkce / *Name and function*

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VASTAVUSDEKLARATSIOON / *DECLARATION OF CONFORMITY*

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

Ettevõte kinnitab oma ainuvastusel, et / *We declare under our sole responsibility that*

meditsiiniseade / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Nimi, tüüp või mudel, partii või seerianumber, võimalikud allikad ja osad / *Name, type or model, batch or serial number, possibly sources and number of items*	Artiklite loendit vt lisast / *List of Articles see Annex*
EMDN-kood / *EMDN-Code* GMDN-i kood / *GMDN code* UMDNS-i kood / *UMDNS code* Põhi-UDI-DI / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
klassil / *of class*	IIa
kooskõlas reegliga / *according to rule*	8-1 kooskõlas meditsiiniseadme määrusega 2017/745 lisaga VIII / *according to Annex VIII of Medical Device Regulation 2017/745*

vastab kõigile meditsiiniseadme määruse 2017/745 sätetele, mis seadmele kohaldub. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Kehtivad harmoniseeritud standardid, riiklikud standardid ja muud normatiivdokumendid / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Muid rakenduvaid standardeid vt tehnilistest dokumentidest tootele GLUMA Bond Universal / GLUMA Ceramic Primer, Version 2 *Further Applied standards see Technical Documentation of* *Product* GLUMA Bond Universal / GLUMA Ceramic Primer, *Version 2*
Vastavushindamismenetlus vastavalt / *Conformity assessment procedure acc. to*	meditsiiniseadmete määruse 2017/745 IX. lisa, I. peatükk, 2. ja 3. jaotis ning III. peatükk *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Teavitatud asutus / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Saksamaa CE 0197
Registreerimisnumber / *Registration number*:	HZ 1198082-1
Versiooni number / *Version number*	01
Asendab vastavusdeklaratsiooni alates / *Replaces Declaration of Conformity from*	28.03.2022
Hanau, Aug 15, 2022 Koht, kuupäev / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nimi ja funktsioon / *Name and function*

See vastavusdeklaratsioon kehtib 2 aastat koos toodetud seadmete vastava partii väljastusdokumentidega / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

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Artiklite loend / *List of Articles*
lisa / *Annex*: Vastavusdeklaratsioon / *Declaration of Conformity*

Meditsiiniseade / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Versiooni number / *Version number*	**V02**
Asendab lisa alates / *Replaces Annex from*	**V01, 28.03.2022**
See artiklite loend kehtib vastavusdeklaratsiooni versiooni kohta / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 2022

Koht, kuupäev / *Place, date*

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

Nimi ja funktsioon / *Name and function*

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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 Bond Universal / GLUMA Ceramic Primer**
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 ++J0141103BA01010104cLA
de la clase / *of class*	IIa
de acuerdo con la norma / *according to rule*	8-1 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 4049 - Dentistry– Polymer-based restorative materials Para otras normas aplicadas consulte la documentación técnica del producto GLUMA Bond Universal / GLUMA Ceramic Primer, versión 2 *Further Applied standards see Technical Documentation of Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, Version 2*
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*	28.03.2022
Hanau, Aug 15, 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.*

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Lista de artículos / *List of Articles*
Anexo / *Annex*: Declaración de conformidad / *Declaration of Conformity*

El producto sanitario / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Número de versión / *Version number*	**V02**
Sustituye al Anexo del / *Replaces Annex from*	**V01, 28.03.2022**
Esta lista de artículos es válida para la versión de la declaración de conformidad / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 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*

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ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ / *DECLARATION OF CONFORMITY*

Επωνυμία και διεύθυνση εταιρείας / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Γερμανία / *Germany* *SRN: DE-MF-000007705*

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

το ιατροτεχνολογικό προϊόν / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Επωνυμία, τύπος ή μοντέλο, παρτίδα ή αριθμός σειράς, πιθανές πηγές και αριθμός ειδών / *Name, type or model, batch or serial number, possibly sources and number of items*	Κατάλογος ειδών Παράρτημα / *List of Articles see Annex*
Κωδικός EMDN / *EMDN-Code* Κωδικός GMDN / *GMDN code* Κωδικός UMDNS / *UMDNS code* Βασικό UDI-DI / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
κλάσης / *of class*	IIa
σύμφωνα με τον κανόνα / *according to rule*	8-1 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 4049 - Dentistry– Polymer-based restorative materials Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική τεκμηρίωση του προϊόντος GLUMA Bond Universal / GLUMA Ceramic Primer, έκδοση 2 *Further Applied standards see Technical Documentation of* *Product* GLUMA Bond Universal / GLUMA Ceramic Primer, *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 *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Κοινοποιημένος οργανισμός / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Γερμανία CE 0197
Αριθμός καταχώρησης / *Registration number*:	HZ 1198082-1
Αριθμός έκδοσης / *Version number*	01
Αντικαθιστά τη δήλωση συμμόρφωσης από / *Replaces Declaration of Conformity from*	28.03.2022
Hanau, Aug 15, 2022	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Τόπος, ημερομηνία / *Place, 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.*

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

Το ιατροτεχνολογικό προϊόν / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Αριθμός έκδοσης / *Version number*	**V02**
Αντικαθιστά το Παράρτημα από / *Replaces Annex from*	**V01, 28.03.2022**
Αυτός ο κατάλογος προϊόντων ισχύει για την έκδοση δήλωσης συμμόρφωσης / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 2022

Τόπος, ημερομηνία / *Place, date*

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

Ονοματεπώνυμο και τίτλος / *Name and function*

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IZJAVA O USKLAĐENOSTI / *DECLARATION OF CONFORMITY*

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

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

medicinski proizvod / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Naziv, tip ili model, broj serije, po mogućnosti izvori i broj stavki / *Name, type or model, batch or serial number, possibly sources and number of items*	Popis artikala, pogledajte Dodatak / *List of Articles see Annex*
šifra EMDN / *EMDN-Code* šifra GMDN / *GMDN code* šifra UMDNS / *UMDNS code* osnovni UDI-DI / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
klase / *of class*	IIa
u skladu s pravilom / *according to rule*	8-1 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 4049 - Dentistry– Polymer-based restorative materials Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod GLUMA Bond Universal / GLUMA Ceramic Primer, verzija 2 *Further Applied standards see Technical Documentation of* *Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, 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 *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Obaviješteno tijelo / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Njemačka CE 0197
Registracijski broj / *Registration number*:	HZ 1198082-1
Broj verzije / *Version number*	01
Zamjenjuje Izjavu o usklađenosti od / *Replaces Declaration of Conformity from*	28.03.2022
Hanau, Aug 15, 2022 Mjesto, datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Ime i funkcija / *Name and function*

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

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

Medicinski proizvod / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Broj verzije / *Version number*	**V02**
Zamjenjuje Dodatak od / *Replaces Annex from*	**V01, 28.03.2022**
Ovaj popis artikala valjan je za verziju izjave u sukladnosti / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 2022

Mjesto, datum / *Place, date*

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

Ime i funkcija / *Name and function*

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MEGFELELŐSÉGI NYILATKOZAT / *DECLARATION OF CONFORMITY*

A vállalat neve és címe / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Németország / *Germany* *SRN: DE-MF-000007705*

Kizárólagos felelősségünkre kijelentjük, hogy / *We declare under our sole responsibility that*

az orvostechnikai eszköz / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Név, típus vagy modell, tétel vagy sorozatszám, esetleg források és tételek száma / *Name, type or model, batch or serial number, possibly sources and number of items*	A cikkek listáját lásd a mellékletben / *List of Articles see Annex*
EMDN kód / *EMDN-Code* GMDN kód / *GMDN code* UMDNS kód / *UMDNS code* Alapvető UDI-DI / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
osztálya / *of class*	IIa
a következő szabály szerint / *according to rule*	8-1 az orvostechnikai eszközökről szóló 2017/745 rendelet VIII. melléklete szerint / *according to Annex VIII of Medical Device Regulation 2017/745*

megfelel az orvostechnikai eszközökről szóló, 2017/745 rendelet valamennyi rá vonatkozó rendelkezésének. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Alkalmazott harmonizált szabványok, nemzeti szabványok vagy más normatív dokumentumok / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials További alkalmazott szabványokat lásd a műszaki dokumentációban, termék: GLUMA Bond Universal / GLUMA Ceramic Primer, 2. verzió *Further Applied standards see Technical Documentation of* *Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, Version 2*
Megfelelőségértékelési eljárás a következő szerint /*Conformity assessment procedure acc. to*	Az orvostechnikai eszközökről szóló, 2017/745 rendelet IX. függeléke, az I. fejezet 2. és 3. szakasza, és a III. fejezet *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Bejelentett szervezet / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Németország CE 0197
Regisztrációs szám / *Registration number*:	HZ 1198082-1
Verziószám / *Version number*	01
Felváltja a megfelelőségi nyilatkozatot ettől / *Replaces Declaration of Conformity from*	28.03.2022
Hanau, Aug 15, 2022 Hely, dátum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Név és funkció / *Name and function*

Ez a megfelelőségi nyilatkozat 2 évig érvényes a gyártott eszközök adott tételére vonatkozó kibocsátási dokumentumokkal együtt. / This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.

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KULZER
MITSUI CHEMICALS GROUP

Cikkek listája / *List of Articles*
Melléklet / *Annex*: Megfelelőségi nyilatkozat / *Declaration of Conformity*

Az orvostechnikai eszköz / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Verziószám / *Version number*	**V02**
Felváltja a mellékletet ettől / *Replaces Annex from*	**V01, 28.03.2022**
Ez a tétellista a megfelelőségi nyilatkozat következő verziójához érvényes / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 2022

Hely, dátum / *Place, date*

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

Név és funkció / *Name and function*

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ATITIKTIES DEKLARACIJA / *DECLARATION OF CONFORMITY*

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

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

medicinos prietaisas / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Pavadinimas, tipas arba modelis, partija arba serijos numeris, galimi šaltiniai ir elementų skaičius / *Name, type or model, batch or serial number, possibly sources and number of items*	Prekių sąrašo ieškokite Priede / *List of Articles see Annex*
EMDN kodas / *EMDN-Code* GMDN kodas / *GMDN code* UMDNS kodas / *UMDNS code* Pagrindinis UDI-DI / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
klasės / *of class*	IIa
pagal taisyklę / *according to rule*	8-1 Pagal Medicinos prietaisų reglamento 2017/745 VIII priedą / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Taikomi harmonizuotieji standartai, nacionaliniai standartai ar kiti normatyviniai dokumentai / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials atkuriamosiomis medžiagomis Kitus taikomus standartus žr. produkto GLUMA Bond Universal / GLUMA Ceramic Primer, techninėje dokumentacijoje, 2 versijoje *Further Applied standards see Technical Documentation of* *Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, Version 2*
]Atitikties patvirtinimo procedūra pagal / *Conformity assessment procedure acc. to*	Medicinos priemonių reglamento 2017/745 IX priedas, I skyrius, 2 ir 3 straipsniai bei III skyrius *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikuotoji įstaiga / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Vokietija CE 0197
Registracijos numeris / *Registration number*:	HZ 1198082-1
Versijos numeris / *Version number*	01
Pakeičia atitikties deklaraciją nuo / *Replaces Declaration of Conformity from*	28.03.2022
Hanau, Aug 15, 2022	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Vieta, data / *Place, date*	Vardas, pavardė ir pareigos / *Name and function*

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

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

Medicinos prietaisas / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Versijos numeris / *Version number*	**V02**
Pakeičia Priedą nuo / *Replaces Annex from*	**V01, 28.03.2022**
Šis straipsnių sąrašas tinka atitikties deklaracijai, kurios versija yra / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 2022

Vieta, data / *Place, date*

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

Vardas, pavardė ir pareigos / *Name and function*

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ATBILSTĪBAS DEKLARĀCIJA / *DECLARATION OF CONFORMITY*

Uzņēmuma nosaukums un adrese / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Vācija / *Germany* *SRN: DE-MF-000007705*

Mēs vienīgi uz savu atbildību deklarējam, ka / *We declare under our sole responsibility that*

medicīniskā ierīce / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Preču nosaukums, tips vai modelis, partijas vai sērijas numurs, iespējamie avoti un skaits / *Name, type or model, batch or serial number, possibly sources and number of items*	Preču sarakstu skatiet pielikumā / *List of Articles see Annex*
EMDN kods / *EMDN-Code* GMDN kods / *GMDN code* UMDNS kods / *UMDNS code* Pamata UDI-DI / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
klase / *of class*	IIa
saskaņā ar noteikumu / *according to rule*	8-1 saskaņā ar Medicīnisko ierīču regulas 2017/745 VIII pielikumu / *according to Annex VIII of Medical Device Regulation 2017/745*

atbilst visiem tiem Medicīnisko ierīču regulas 2017/745 noteikumiem, kas uz to attiecas. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Izmantotie saskaņotie standarti, nacionālie standarti vai citi normatīvie dokumenti / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Citus izmantotos standartus skatiet tehniskajā dokumentācijā par produktu GLUMA Bond Universal / GLUMA Ceramic Primer, 2. versija *Further Applied standards see Technical Documentation of* *Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, Version 2*
Atbilstības novērtēšanas procedūra saskaņā ar / *Conformity assessment procedure acc. to*	Medicīnisko ierīču regulas 2017/745 IX pielikumu, I nodaļu, 2. un 3. iedaļu un III nodaļu *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Pilnvarotā iestāde / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Vācija CE 0197
Reģistrācijas numurs / *Registration number*:	HZ 1198082-1
Versijas numurs / *Version number*	01
Aizstāj atbilstības deklarāciju, kas datēta ar / *Replaces Declaration of Conformity from*	28.03.2022
Hānava Aug 15, 2022	v.i. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Vieta, datums / *Place, date*	Vārds, uzvārds un amats / *Name and function*

Šis paziņojums par atbilstību ir derīgs 2 gadus saistībā ar ražoto ierīču atbilstošās partijas izlaišanas dokumentiem. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

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Preču saraksts / *List of Articles*
Pielikums / *Annex*: Atbilstības deklarācija / *Declaration of Conformity*

Medicīniskā ierīce / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Versijas numurs / *Version number*	**V02**
Aizstāj pielikumu, kas datēts ar / *Replaces Annex from*	**V01, 28.03.2022**
Šis izstrādājumu saraksts ir derīgs šādai atbilstības deklarācijas versijai / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hānava Nov 23, 2022

Vieta, datums / *Place, date*

i.V.

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

Vārds, uzvārds un amats / *Name and function*

DocuSign Envelope ID: C7F58075-D31C-4621-86EC-BC9C3CEC2ED7

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 Bond Universal / GLUMA Ceramic Primer**
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 ++J0141103BA01010104cLA
van klasse / *of class*	IIa
in overeenstemming met regelgeving / *according to rule*	8-1 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 4049 - Dentistry– Polymer-based restorative materials Voor overige toegepaste normen, zie technische documenten van product GLUMA Bond Universal / GLUMA Ceramic Primer, versie 2 *Further Applied standards see Technical Documentation of Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, 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 *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*	28.03.2022
Hanau, Aug 15, 2022	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.*

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

Het medisch hulpmiddel / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Versienummer / *Version number*	**V02**
Vervangt de bijlage van / *Replaces Annex from*	**V01, 28.03.2022**
Deze artikellijst is geldig voor de conformiteitsverklaring, versie / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 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*

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DEKLARACJA ZGODNOŚCI / *DECLARATION OF CONFORMITY*

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

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

wyrób medyczny / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
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* Kod wyrobu wg GMDN / *GMDN code* Kod wyrobu wg UMDNS / *UMDNS code* Kod Basic UDI-DI / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
klasy / *of class*	IIa
zgodnie z regułą / *according to rule*	8-1 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 4049 - Dentistry– Polymer-based restorative materials Pozostałe stosowane normy znajdują się w dokumentacji technicznej produktu GLUMA Bond Universal / GLUMA Ceramic Primer, wersja 2 *Further Applied standards see Technical Documentation of Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, 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 *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 Tillystrasse 2 90431 Nürnberg/Niemcy CE 0197
Numer rejestracyjny / *Registration number*:	HZ 1198082-1
Numer wersji / *Version number*	01
Zastępuje Deklarację zgodności z / *Replaces Declaration of Conformity from*	28.03.2022
Hanau, Aug 15, 2022	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **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*.

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

Wyrób medyczny / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Numer wersji / *Version number*	**V02**
Zastępuje załącznik z dnia / *Replaces Annex from*	**V01, 28.03.2022**
Poniższa lista artykułów obowiązuje dla następujących wersji deklaracji zgodności / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 2022

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*

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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 Bond Universal / GLUMA Ceramic Primer**
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 ++J0141103BA01010104cLA
din clasa / *of class*	IIa
în conformitate cu regula / *according to rule*	8-1 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 4049 - Dentistry– Polymer-based restorative materials Alte standarde aplicate, vezi documentația tehnică a Produsului GLUMA Bond Universal / GLUMA Ceramic Primer, Versiunea 2 *Further Applied standards see Technical Documentation of* *Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, 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 *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*	28.03.2022
Hanau, Aug 15, 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.*

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

Dispozitivul medical / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Număr versiune / *Version number*	**V02**
Înlocuiește Anexa de la / *Replaces Annex from*	**V01, 28.03.2022**
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	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 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*

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IZJAVA O SKLADNOSTI / *DECLARATION OF CONFORMITY*

Ime in naslov podjetja / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Nemčija / *Germany* *SRN: DE-MF-000007705*

Z izključno odgovornostjo izjavljamo, da / *We declare under our sole responsibility that*

medicinski pripomoček / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Ime, vrsta ali model, številka šarže ali serijska številka, po možnosti izvor in število izdelkov / *Name, type or model, batch or serial number, possibly sources and number of items*	Seznam artiklov je na voljo v Prilogi / *List of Articles see Annex*
Koda EMDN / *EMDN-Code* Koda GMDN / *GMDN code* Koda UMDNS / *UMDNS code* Osnovni UDI-DI / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
razreda / *of class*	IIa
v skladu s členom / *according to rule*	8-1, v skladu s Prilogo VIII Uredbe o medicinskih pripomočkih 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

izpolnjuje vse določbe Uredbe o medicinskih pripomočkih 2017/745, ki veljajo zanj. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Uveljavljeni usklajeni standardi, nacionalni standardi ali drugi normativni dokumenti / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Drugi uveljavljeni standardi so na voljo v Tehnični dokumentaciji izdelka GLUMA Bond Universal / GLUMA Ceramic Primer, različica 2 *Further Applied standards see Technical Documentation of* *Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, Version 2*
Postopek ugotavljanja skladnosti v skladu z / *Conformity assessment procedure acc. to*	Uredbo o medicinskih pripomočkih 2017/745, Priloga IX, poglavje I, oddelka 2 in 3, poglavje III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Priglašeni organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Nemčija CE 0197
Registrska številka / *Registration number*:	HZ 1198082-1
Številka različice / *Version number*	01
Nadomešča Izjavo o skladnosti z dne / *Replaces Declaration of Conformity from*	28.03.2022
Hanau, Aug 15, 2022 Kraj, datum / *Place, date*	i.V. zastopnica Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Ime in položaj / *Name and function*

Ta izjava o skladnosti je veljavna 2 leti v povezavi z dokumenti o izdaji za zadevne serije proizvedenih pripomočkov. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

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Seznam artiklov / *List of Articles*
Priloga / *Annex*: Izjava o skladnosti / *Declaration of Conformity*

Medicinski pripomoček / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Številka različice / *Version number*	**V02**
Nadomešča Prilogo z dne / *Replaces Annex from*	**V01, 28.03.2022**
Ta seznam izdelkov velja za naslednjo različico izjave o skladnosti / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

i.V.

Hanau, Nov 23, 2022

Kraj, datum / *Place, date*

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

Ime in položaj / *Name and function*

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VYHLÁSENIE O ZHODE / *DECLARATION OF CONFORMITY*

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

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

zdravotnícka pomôcka / *the medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Názov, typ alebo model, číslo šarže alebo sériové číslo, prípadne zdroje a počet kusov / *Name, type or model, batch or serial number, possibly sources and number of items*	Zoznam položiek je uvedený v prílohe / *List of Articles see Annex*
Kód EMDN / *EMDN-Code* Kód GMDN / *GMDN code* Kód UMDNS / *UMDNS code* Základné identifikačné číslo UDI-DI / *Basic UDI-DI*	Q010101 34782 10-034 ++J0141103BA01010104cLA
triedy / *of class*	IIa
podľa pravidla / *according to rule*	8-1 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 4049 - Dentistry– Polymer-based restorative materials Ďalšie použité normy nájdete v technickej dokumentácii verzie 2 k produktu GLUMA Bond Universal / GLUMA Ceramic Primer *Further Applied standards see Technical Documentation of* *Product* GLUMA Bond Universal / GLUMA Ceramic Primer*, 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 *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikovaný orgán / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Nemecko CE 0197
Registračné číslo / *Registration number*:	HZ 1198082-1
Číslo verzie / *Version number*	01
Nahrádza vyhlásenie o zhode z / *Replaces Declaration of Conformity from*	28.03.2022
Hanau, Aug 15, 2022	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Miesto, dátum / *Place, date*	Meno a funkcia / *Name and function*

Toto vyhlásenie o zhode je platné 2 roky v súvislosti s dokumentmi o uvoľnení príslušnej šarže vyrobených pomôcok / This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.

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

Zdravotnícka pomôcka / *The medical device*	**GLUMA Bond Universal / GLUMA Ceramic Primer**
Číslo verzie / *Version number*	**V02**
Nahrádza prílohu z / *Replaces Annex from*	**V01, 28.03.2022**
Tento zoznam tovaru je platný pre vyhlásenie o zhode, verzia / *This article list is valid for the declaration of conformity version*	**V01**

UDI-DI	Article number	Article Name
+J014660614210	66061421	GLUMA BOND UNIVERSAL BOTTLE REFILL 1X4ML
+J014660614220	66061422	GLUMA BOND UNIVERSAL BOTTLE VALUE PACK
+J014660647410	66064741	GLUMA BOND UNIVERSAL BOTTLE SAMPLE 1X2ML
+J014660614250	66061425	GLUMA CERAMIC PRIMER 1X4ML
+J014660961070	66096107	PROC GLUMA BOND UNIVERSAL ONE KIT 1X4ML
+J014660961120	66096112	PROC GLUMA BOND UNIVERSAL KIT 1X4ML

Hanau, Nov 23, 2022

Miesto, dátum / *Place, date*

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

Meno a funkcia / *Name and function*

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Betreff: Mit DocuSign abschließen: Gluma Bond Universal Annex komplett.pdf
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Signaturen: 15
Umschlagersteller:
Zertifikatsseiten: 4
Initialen: 0
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Leipziger Str. 2
Umschlag-ID-Stempel: Aktiviert
Hanau, Hessen 63450
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Anette.Stadtfeld@kulzer-dental.com
IP-Adresse: 89.246.249.146

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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: 77.179.118.94	Gesendet: 23.11.2022 11:37:16 Eingesehen: 23.11.2022 15:40:58 Signiert: 23.11.2022 15:41:22

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:
Akzeptiert: 23.11.2022 15:40:58
ID: 4c42c5d7-527a-4856-bcdc-3987e4c00bec

Vor-Ort-Unterzeichner – Ereignisse	Signatur	Zeitstempel

Bearbeiterversandereignisse	Status	Zeitstempel

Beauftragtenzustellereignisse	Status	Zeitstempel

Vermittlerversandereignisse	Status	Zeitstempel

Zertifizierter Versand - Ereignisse	Status	Zeitstempel

Kopienereignisse	Status	Zeitstempel

Zeugen-Ereignisse	Signatur	Zeitstempel

Notarereignisse	Signatur	Zeitstempel

Umschlagereignisse – Überblick	Status	Zeitstempel
Umschlag gesendet	Hash-codiert/verschlüsselt	23.11.2022 11:37:16
Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	23.11.2022 15:40:58
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	23.11.2022 15:41:22
Abgeschlossen	Sicherheitsprüfung ausgeführt	23.11.2022 15:41:22

Zahlungen	Status	Zeitstempel

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You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
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To advise Kulzer GmbH of your new email address

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ii. send us an email to dieter.lorber@kulzer-dental.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

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Quellumschlag:
Dokumentenseiten: 24
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Initialen: 0
Anette Stadtfeld
Signatur mit Anleitung: Aktiviert
Leipziger Str. 2
Umschlag-ID-Stempel: Aktiviert
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Eintragsverfolgung

Status: Original
15.08.2022 10:57:51
Inhaber: Anette Stadtfeld
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Standort: DocuSign

Unterzeichnerereignisse	Signatur	Zeitstempel
Matthias Hartmann matthias.hartmann@kulzer-dental.com PRRC Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	 Signaturübernahme: Hochgeladenes Signaturbild Mit IP-Adresse: 77.190.156.252	Gesendet: 15.08.2022 11:04:26 Eingesehen: 15.08.2022 12:02:50 Signiert: 15.08.2022 12:03:29

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:
Akzeptiert: 15.08.2022 12:02:50
ID: d16aad2e-49ed-4a4d-932d-28c286a15580

Vor-Ort-Unterzeichner – Ereignisse	Signatur	Zeitstempel

Bearbeiterversandereignisse	Status	Zeitstempel

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Umschlag gesendet	Hash-codiert/verschlüsselt	15.08.2022 11:04:26
Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	15.08.2022 12:02:50
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	15.08.2022 12:03:29
Abgeschlossen	Sicherheitsprüfung ausgeführt	15.08.2022 12:03:29

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