


KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Name und Adresse der Firma / <i>Name and address of the company</i>	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 / <i>the medical device</i>	GLUMA Bond Universal / GLUMA Ceramic Primer
Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl / <i>Name, type or model, batch or serial number, possibly sources and number of items</i>	Artikelliste siehe Anhang / <i>List of Articles see Annex</i>
EMDN-Nummer / <i>EMDN-Code</i> GMDN-Nummer / <i>GMDN code</i>	Q010101 34782 62474
UMDNS-Nummer / <i>UMDNS code</i> Basis-UDI-DI / <i>Basic UDI-DI</i>	10-034 ++J0141103BA01010104cLA
der Klasse / <i>of class</i>	Ila
nach Regel / <i>according to rule</i>	8-1 nach Anhang VIII der Medizinprodukte-Verordnung, 2017/745 / <i>according to Annex VIII of Medical Device Regulation 2017/745</i>
allen Anforderungen der Medizinprodukte-Verordnung 2017/745 entspricht, die anwendbar sind / <i>meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.</i>	
Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente / <i>Applied harmonised standards, national standards or other normative documents</i>	Angewandte Normen siehe Version 03 der Technischen Dokumentation von Produkt GLUMA Bond Universal / GLUMA Ceramic Primer / <i>Applied standards see Technical Documentation of Product GLUMA Bond Universal / GLUMA Ceramic Primer, Version 03</i>
Konformitätsbewertungsverfahren nach / <i>Conformity assessment procedure acc. to</i>	Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I, Abschnitt 2 und 3 and Kapitel III <i>Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III</i>
Benannte Stelle / <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Germany CE 0197
Registrierungsnr. / <i>Registration No.:</i>	HZ 1198082-1
Versionsnummer / <i>Version number</i>	03
Ersetzt Konformitätserklärung vom / <i>Replaces Declaration of Conformity from</i>	08.08.2024
Hanau, 21.10.2024	i.V.  Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services Kulzer GmbH
Ort, Datum / <i>Place, date</i>	<hr/> Name und Funktion / <i>Name and function</i>

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 / <i>for the medical device</i>	GLUMA Bond Universal / GLUMA Ceramic Primer
Versionsnummer Artikelliste/ <i>Version number article list</i>	06
Ersetzt Artikelliste vom / <i>Replaces article list from</i>	21.10.2024
Diese Artikelliste ist gültig für die Konformitätserklärung Version/ <i>This article list is valid for the declaration of conformity version</i>	03

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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML

Hanau, 15.09.2025

Ort, Datum / *Place, date*



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

Name und Funktion / *Name and function*

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*

Q010101
 34782
 62474

Код по UMDNS / *UMDNS code*
 Основна UDI-DI идентификация / *Basic UDI-DI*

10-034
 ++J0141103BA01010104cLA

от клас / *of class*

Ila

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

Други приложени стандарти, вижте техническата
 документация на продукт GLUMA Bond Universal / GLUMA
 Ceramic Primer Версия 03
Further Applied standards see Technical Documentation of
Product GLUMA Bond Universal / GLUMA Ceramic Primer,
Version 03

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*

03

Заменя Декларация за съответствие от /
Replaces Declaration of Conformity from

08.08.2024



Ханану, 21.10.2024

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

Място, дата / *Place, date*

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.



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

Медицинското изделие / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Номер на версия / **06**
Version number

Заменя Приложението от / **21.10.2024**
Replaces Annex from

Този списък със статии е валиден във връзка с **03**
 декларацията за съответствие, версия / *This*
This article list is valid for the declaration of
conformity version

UDI-DI / UDI-DI	Номер на артикул / Article number	Наименование / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML

Ханау, 15.09.2025

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

Място, дата / *Place, date*

Име и длъжност / *Name and function*

**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-000007705Prohlašujeme 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 itemsSeznam položek je uveden v příloze /
List of Articles see AnnexKód EMDN / EMDN-Code
Kód GMDN / GMDN codeQ010101
34782
62474Kód UMDNS / UMDNS code
Základní UDI-DI / Basic UDI-DI10-034
++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
documentsDalší použité normy najdete v technické dokumentaci k
výrobku GLUMA Bond Universal / GLUMA Ceramic Primer,
verze 03
Further Applied standards see Technical Documentation of
Product GLUMA Bond Universal / GLUMA Ceramic Primer,
Version 03Procedura posouzení shody podle /
Conformity assessment procedure acc. tonařízení 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

03

Nahrazuje Prohlášení o shodě ze dne /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

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.

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

Zdravotnický prostředek / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Číslo verze / *Version number* **06**

Nahrazuje přílohu ze dne / **21.10.2024**
Replaces Annex from

Tento seznam zboží platí pro verzi **03**
prohlášení o shodě / *This article list is valid*
for the declaration of conformity version:

UDI-DI / UDI-DI	Číslo zboží / Article number	Název / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML



Hanau, 15.09.2025

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

Místo, datum / *Place, date*

Jméno a funkce / *Name and function*

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

Ettevõtte 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

Q010101
 34782
 62474

UMDNS-i kood / UMDNS code
 Põhi-UDI-DI / Basic UDI-DI

10-034
 ++J0141103BA01010104cLA

klassil / of class

Ila

kooskõlas reegluga / 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

Muid rakenduvaid standardeid vt tehnilistest
 dokumentidest tootele GLUMA Bond Universal / GLUMA Ceramic
 Primer, Version 03
 Further Applied standards see Technical Documentation of
 Product GLUMA Bond Universal / GLUMA Ceramic Primer,
 Version 03

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

03

Asendab vastavusdeklaratsiooni alates /
 Replaces Declaration of Conformity from

08.08.2024



Hanau, 21.10.2024

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

Koht, kuupäev / Place, date

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.

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

Meditsiiniseade / <i>The medical device</i>	GLUMA Bond Universal / GLUMA Ceramic Primer
Versiooni number / <i>Version number</i>	06
Asendab lisa alates / <i>Replaces Annex from</i>	21.10.2024
See artiklite loend kehtib vastavusdeklaratsiooni versiooni kohta / <i>This article list is valid for the declaration of conformity version</i>	03

UDI-DI / UDI-DI	Artikli number / Article number	Nimi / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML



Hanau, 15.09.2025

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

Koht, kuupäev / *Place, date*

Nimi ja funktsioon / *Name and function*

**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-00007705**Δηλώνουμε με δική μας ευθύνη ότι / We declare under our sole responsibility that**

το ιατροτεχνολογικό προϊόν / the medical device

GLUMA Bond Universal / GLUMA Ceramic PrimerΕπωνυμία, 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 codeQ010101
34782
62474Κωδικός UMDNS / UMDNS code
Βασικό UDI-DI / Basic UDI-DI10-034
++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 documentsΓια περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική
τεκμηρίωση του
προϊόντος GLUMA Bond Universal / GLUMA Ceramic Primer,
έκδοση 03
Further Applied standards see Technical Documentation of
Product GLUMA Bond Universal / GLUMA Ceramic Primer,
Version 03Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με
/ Conformity assessment procedure acc. toΚανονισμός 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

03

Αντικαθιστά τη δήλωση συμμόρφωσης από /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

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

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

Το ιατροτεχνολογικό προϊόν / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Αριθμός έκδοσης / **06**
Version number

Αντικαθιστά το Παράρτημα από / **21.10.2024**
Replaces Annex from

Αυτός ο κατάλογος προϊόντων ισχύει για την **03**
έκδοση δήλωσης συμμόρφωσης / *This article*
list is valid for the declaration of conformity
version

UDI-DI / UDI-DI	Αριθμός είδους / Article number	Όνομα / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML




Hanau, 15.09.2025

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

Τόπος, ημερομηνία / *Place, date*

Όνοματεπώνυμο και τίτλος / *Name and function*

IZJAVA O USKLAĐENOSTI / DECLARATION OF CONFORMITY

Naziv i adresa tvrtke / <i>Name and address of the company</i>	Kulzer GmbH Leipziger Straße 2, 63450 Hanau Njemačka / Germany SRN: DE-MF-00007705
Izjavljujemo pod punom odgovornošću da / We declare under our sole responsibility that	
medicinski proizvod / <i>the medical device</i>	GLUMA Bond Universal / GLUMA Ceramic Primer
Naziv, tip ili model, broj serije, po mogućnosti izvori i broj stavki / <i>Name, type or model, batch or serial number, possibly sources and number of items</i>	Popis artikala, pogledajte Dodatak / <i>List of Articles see Annex</i>
šifra EMDN / <i>EMDN-Code</i>	Q010101
šifra GMDN / <i>GMDN code</i>	34782
šifra UMDNS / <i>UMDNS code</i>	62474
osnovni UDI-DI / <i>Basic UDI-DI</i>	10-034
klase / <i>of class</i>	++J0141103BA01010104cLA
u skladu s pravilom / <i>according to rule</i>	IIa
ispunjava sve odredbe Uredbe 2017/745 o medicinskim proizvodima koje se na njega odnose. / <i>meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.</i>	
Primijenjene usklađene norme, državne norme ili drugi normativni dokumenti / <i>Applied harmonised standards, national standards or other normative documents</i>	Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod GLUMA Bond Universal / GLUMA Ceramic Primer, verzija 03 <i>Further Applied standards see Technical Documentation of Product GLUMA Bond Universal / GLUMA Ceramic Primer, Version 03</i>
Postupak procjene usklađenosti prema / <i>Conformity assessment procedure acc. to</i>	Prilog IX Uredbi 2017/745 o medicinskim proizvodima, Poglavlje I, Odjeljak 2 i 3 te Poglavlje III <i>Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III</i>
Obaviješteno tijelo / <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Njemačka
Registracijski broj / <i>Registration number</i>	CE 0197
Broj verzije / <i>Version number</i>	HZ 1198082-1
Zamjenjuje Izjavu o usklađenosti od / <i>Replaces Declaration of Conformity from</i>	03
Hanau, 21.10.2024	08.08.2024 
Mjesto, datum / <i>Place, date</i>	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services Kulzer GmbH
	Ime i funkcija / <i>Name and function</i>

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



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

Medicinski proizvod / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Broj verzije / **06**
Version number

Zamjenjuje Dodatak od / **21.10.2024**
Replaces Annex from

Ovaj popis artikala valjan je za verziju izjave **03**
u sukladnosti / *This article list is valid for the*
declaration of conformity version

UDI-DI / UDI-DI	Broj artikla / Article number	Naziv / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML

Hanau, 15.09.2025

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

Mjesto, datum / *Place, date*

Ime i funkcija / *Name and function*

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 orvostechikai 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

Q010101
34782
62474

UMDNS kód / UMDNS code
Alapvető UDI-DI / Basic UDI-DI

10-034
++J0141103BA01010104cLA

osztálya / of class

Ila

a következő szabály szerint / according to rule

8-1 az orvostechikai eszközökről szóló 2017/745 rendelet VIII.
melléklete szerint / according to Annex VIII of Medical Device
Regulation 2017/745

**megfelel az orvostechikai 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

További alkalmazott szabványokat lásd a műszaki dokumentációban,
termék: GLUMA Bond Universal / GLUMA Ceramic Primer, 03. verzió
Further Applied standards see Technical Documentation of
Product GLUMA Bond Universal / GLUMA Ceramic Primer, Version 03

Megfelelőségértékelési eljárás a következő szerint /
Conformity assessment procedure acc. to

Az orvostechikai 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

03

Felváltja a megfelelőségi nyilatkozatot ettől /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024


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

Kulzer GmbH

Hely, dátum / Place, date

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.



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

Az orvostechnikai eszköz / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Verziószám / **06**
Version number

Felváltja a mellékletet ettől / **21.10.2024**
Replaces Annex from

Ez a tételista a megfelelőségi nyilatkozat **03**
következő verziójához érvényes / *This article*
list is valid for the declaration of conformity
version

UDI-DI / UDI-DI	Cikkszám / Article number	Név / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML

Hanau, 15.09.2025

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

Hely, dátum / *Place, date*

Név és funkció / *Name and function*

**ATITIKTIES DEKLARACIJA / DECLARATION OF CONFORMITY**Bendrovės pavadinimas ir adresas /
*Name and address of the company***Kulzer GmbH**
Leipziger Straße 2, 63450 Hanau
Vokietija / Germany
SRN: DE-MF-00007705Prisiimdami visą atsakomybę pareiškiame, kad / *We declare under our sole responsibility that*
medicinos prietaisais / *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*Q010101
34782
62474UMDNS kodas / *UMDNS code*
Pagrindinis UDI-DI / *Basic UDI-DI*10-034
++J0141103BA01010104cLAklasės / *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*atkuriamosiomis medžiagomis Kitus taikomus standartus žr.
produkto GLUMA Bond Universal / GLUMA Ceramic Primer,
techninėje dokumentacijoje, 03 versijoje
Further Applied standards see Technical Documentation of
Product GLUMA Bond Universal / GLUMA Ceramic Primer,
*Version 03*Atitikties patvirtinimo procedūra pagal /
*Conformity assessment procedure acc. to*Medicinos priemonių reglamento 2017/745 IX priedas, I skyrius, 2 ir
3 straipsniai bei III skyrius*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section*
*2 and 3 and Chapter III*Notifikuotoji įstaiga / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Vokietija

CE 0197

Registracijos numeris / *Registration number:*

HZ 1198082-1

Versijos numeris / *Version number*

03

Pakeičia atitikties deklaraciją nuo /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

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



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

Medicinos prietaisas / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Versijos numeris / **06**
Version number

Pakeičia Priedą nuo / **21.10.2024**
Replaces Annex from

Šis straipsnių sąrašas tinka atitikties **03**
deklaracijai, kurios versija yra / *This article*
list is valid for the declaration of conformity
version

UDI-DI / UDI-DI	Prekės numeris / Article number	Pavadinimas / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML

Hanau, 15.09.2025

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*

ATBILSTĪBAS DEKLARĀCIJA / DECLARATION OF CONFORMITYUzņēmuma nosaukums un adrese /
*Name and address of the company***Kulzer GmbH**
Leipziger Straße 2, 63450 Hanau
Vācija / *Germany*
SRN: DE-MF-00007705Mēs 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*Q010101
34782
62474UMDNS kods / *UMDNS code*
Pamata UDI-DI / *Basic UDI-DI*10-034
++J0141103BA01010104cLAklase / *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*Citus izmantotos standartus skatiet tehniskajā dokumentācijā par
produktu GLUMA Bond Universal / GLUMA Ceramic Primer,
03. versija
Further Applied standards see Technical Documentation of
Product GLUMA Bond Universal / GLUMA Ceramic Primer,
*Version 03*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*

03

Aizstāj atbilstības deklarāciju, kas datēta ar /
Replaces Declaration of Conformity from

08.08.2024



Hānava 21.10.2024

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

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

Medicīniskā ierīce / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Versijas numurs / **06**
Version number

Aizstāj pielikumu, kas datēts ar / **21.10.2024**
Replaces Annex from

Šis izstrādājumu saraksts ir derīgs šādai **03**
atbilstības deklarācijas versijai / *This article*
list is valid for the declaration of conformity
version

UDI-DI / UDI-DI	Preces numurs / Article number	Nosaukums / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML



15.09.2025
Hānava

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*

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

Q010101
 34782
 62474

Kod wyrobu wg UMDNS / UMDNS code
 Kod Basic UDI-DI / Basic UDI-DI

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

Pozostałe stosowane normy znajdują się w dokumentacji
 technicznej produktu GLUMA Bond Universal / GLUMA Ceramic
 Primer, wersja 03
 Further Applied standards see Technical Documentation of
 Product GLUMA Bond Universal / GLUMA Ceramic Primer,
 Version 03

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

03

Zastępuje Deklarację zgodności z /
 Replaces Declaration of Conformity from

08.08.2024



Hanau, 21.10.2024

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.



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

Wyrób medyczny / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Numer wersji / **06**
Version number

Zastępuje załącznik z dnia / **21.10.2024**
Replaces Annex from

Poniższa lista artykułów obowiązuje dla **03**
następujących wersji deklaracji zgodności /
This article list is valid for the declaration of
conformity version

UDI-DI / UDI-DI	Numer wyrobu / Article number	Nazwa / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML

Hanau, 15.09.2025

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*

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*

Q010101
 34782
 62474

Cod UMDNS / *UMDNS code*
 UDI-DI de bază / *Basic UDI-DI*

10-034
 ++J0141103BA01010104cLA

din clasa / *of class*

Ila

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*

Alte standarde aplicate, vezi documentația tehnică a Produsului
 GLUMA Bond Universal / GLUMA Ceramic Primer, Versiunea 03
 Further Applied standards see *Technical Documentation of
 Product GLUMA Bond Universal / GLUMA Ceramic Primer,
 Version 03*

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*

03

Înlocuiește Declarația de conformitate din /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

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 / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Număr versiune / **06**
Version number

Înlocuiește Anexa de la / **21.10.2024**
Replaces Annex from

Această listă de articole este valabilă pentru **03**
 declarația de conformitate versiunea / *This*
article list is valid for the declaration of
conformity version

UDI-DI / UDI-DI	Număr articol / Article number	Nume / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML



Hanau, 15.09.2025

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

Loc, dată / Place, date

Nume și funcție / Name and function

**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 PrimerIme, 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

Q010101

Koda GMDN / GMDN code

34782

Koda UMDNS / UMDNS code

62474

Osnovni UDI-DI / Basic UDI-DI

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

Drugi uveljavljeni standardi so na voljo v Tehnični dokumentaciji izdelka GLUMA Bond Universal / GLUMA Ceramic Primer, različica 03
Further Applied standards see Technical Documentation of Product GLUMA Bond Universal / GLUMA Ceramic Primer, Version 03Postopek 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

03

Nadomešča Izjavo o skladnosti z dne /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

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

Kraj, datum / Place, date

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.



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

Medicinski pripomoček / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Številka različice / **06**
Version number

Nadomešča Prilogo z dne / **21.10.2024**
Replaces Annex from

Ta seznam izdelkov velja za naslednjo **03**
različico izjave o skladnosti / *This article list is*
valid for the declaration of conformity version

UDI-DI / <i>UDI-DI</i>	Številka artikla / <i>Article number</i>	Ime / <i>Name</i>
+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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML

Hanau, 15.09.2025

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

Kraj, datum / *Place, date*

Ime in položaj / *Name and function*

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*

Q010101
 34782
 62474

Kód UMDNS / *UMDNS code*
 Základné identifikačné číslo UDI-DI / *Basic UDI-DI*

10-034
 ++J0141103BA01010104cLA

triedy / *of class*

Ila

podľa pravidiel / *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*

Ďalšie použité normy nájdete v technickej dokumentácii verzie 03 k produktu GLUMA Bond Universal / GLUMA Ceramic Primer
Further Applied standards see Technical Documentation of Product GLUMA Bond Universal / GLUMA Ceramic Primer, Version 03

Postup posúdenia zhody podľa /
Conformity assessment procedure acc. to

prílohy IX k nariadeniu 2017/745 o zdravotníckych pomôckach, kapitola I, časť 2 a 3 a kapitola III
Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III

Notifikovaný orgán / *Notified Body*

TÜV Rheinland LGA Products GmbH
 Tillystrasse 2
 90431 Nürnberg / Nemecko

CE 0197

Registračné číslo / *Registration number:*

HZ 1198082-1

Číslo verzie / *Version number*

03

Nahrádza vyhlásenie o zhode z /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

i.V.


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

Kulzer GmbH

Miesto, dátum / *Place, date*

Meno a funkcia / *Name and function*

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

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

Zdravotnícka pomôcka / **GLUMA Bond Universal / GLUMA Ceramic Primer**
The medical device

Číslo verzie / **Version number** **06**

Nahrádza prílohu z / **21.10.2024**
Replaces Annex from

Tento zoznam tovaru je platný pre vyhlásenie **03**
o zhode, verzia / *This article list is valid for*
the declaration of conformity version

UDI-DI / UDI-DI	Číslo položky / Article number	Meno / 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
+J014661012570	66101257	PROC GLUMA Bond Universal Simplicity Kit 1x4ML



Hanau, 15.09.2025

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

Miesto, dátum / *Place, date*

Meno a funkcia / *Name and function*