

**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 2Bond**

 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  
 ++J0141103BA01010104bL8

 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*

 Angewandte Normen siehe Version 2 der Technischen  
 Dokumentation von Product **GLUMA 2Bond** / *Applied standards  
 see Technical Documentation of Product **GLUMA 2Bond**, 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

 Registrierungsnummer / *Registration No.:*

HZ 1198082-1


 Versionsnummer / *Version number*

02

 Ersetzt Konformitätserklärung vom /  
*Replaces Declaration of Conformity from*

15.08.2022

Hanau, 08.08.2024

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

 Ort, Datum / *Place, date*

 Name und Funktion / *Name and function*

 Diese Konformitätserklärung ist gültig für 2 Jahre in Verbindung mit den Freigabe-Dokumenten für die jeweilige Charge der  
 produzierten Medizinprodukte / *This statement of conformity is valid for 2 years in connection with the release documents for the  
 respective batch of produced devices.*

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

das Medizinprodukt / **GLUMA 2Bond**  
*for the medical device*


Versionsnummer Artikelliste / **03**  
*Version number article list*

Ersetzt Artikelliste vom / **23.11.2022**  
*Replaces article list from*

Diese Artikelliste ist gültig für die **02**  
 Konformitätserklärung Version / *This article list is*  
*valid for the declaration of conformity version*

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hanau, 08.08.2024

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

Ort, Datum / *Place, date*

Name und Funktion / *Name and function*

**ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ / DECLARATION OF CONFORMITY**Име и адрес на фирмата /  
Name and address of the companyKulzer 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 2Bond**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 itemsСписък с артикули, вижте Приложението /  
List of Articles see AnnexКод по EMDN / EMDN-Code  
Код по GMDN / GMDN code  
Код по UMDNS / UMDNS code  
Основна UDI-DI идентификация / Basic UDI-DIQ010101  
34782  
10-034  
++J0141103BA01010104bL8

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, които 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 documentsДруги приложени стандарти, вижте техническата  
документация на продукт **GLUMA 2Bond** Версия 2  
Further Applied standards see Technical Documentation of  
Product **GLUMA 2Bond**, Version 2Процедура за оценка на съответствието съгласно /  
Conformity assessment procedure acc. toРегламента 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

02

Заменя Декларация за съответствие от /  
Replaces Declaration of Conformity from

15.08.2022

Ханау, 08.08.2024

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 /  
*The medical device* **GLUMA 2Bond**

Номер на версия / *Version number* **03**

Заменя Приложението от /  
*Replaces Annex from* **23.11.2022**

Този списък със статии е валиден във връзка с  
декларацията за съответствие, версия / *This* **02**  
*This article list is valid for the declaration of*  
*conformity version*

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Ханау, 08.08.2024

Място, дата / *Place, date*

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

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-000007705

Prohlašujeme na svou výlučnou zodpovědnost, že / *We declare under our sole responsibility that*  
zdravotnický prostředek / *the medical device* **GLUMA 2Bond**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  
++J0141103BA01010104bL8třídy / *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*Další použité normy najdete v technické dokumentaci k  
výrobku **GLUMA 2Bond**, verze 2  
*Further Applied standards see Technical Documentation of*  
*Product GLUMA 2Bond, 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*

02

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

15.08.2022

Hanau, 08.08.2024

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 2Bond**  
*The medical device*


Číslo verze / **03**  
*Version number*

Nahrazuje přílohu ze dne / **23.11.2022**  
*Replaces Annex from*

Tento seznam zboží platí pro verzi  
prohlášení o shodě / **02**  
*This article list is valid  
for the declaration of conformity version:*

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hanau, 08.08.2024

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

Místo, datum / *Place, date*

Jméno a funkce / *Name and function*

## 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 2Bond**

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  
 ++J0141103BA01010104bL8

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 2Bond**, Version 2  
 Further Applied standards see Technical Documentation of  
 Product **GLUMA 2Bond**, 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

02

Asendab vastavusdeklaratsiooni alates /  
 Replaces Declaration of Conformity from

15.08.2022

Hanau, 08.08.2024

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.



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

Meditsiiniseade / **GLUMA 2Bond**  
*The medical device*

Versiooni number / **03**  
*Version number*


Asendab lisa alates / **23.11.2022**  
*Replaces Annex from*

See artiklite loend kehtib **02**  
vastavusdeklaratsiooni versiooni kohta / *This*  
*article list is valid for the declaration of*  
*conformity version*

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hanau, 08.08.2024

Koht, kuupäev / *Place, date*

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

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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-000007705**Δηλώνουμε με δική μας ευθύνη ότι / We declare under our sole responsibility that**

το ιατροτεχνολογικό προϊόν / the medical device

**GLUMA 2Bond**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-DIQ010101  
34782  
10-034  
++J0141103BA01010104bL8

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 2Bond**, έκδοση 2  
Further Applied standards see Technical Documentation of  
Product **GLUMA 2Bond**, Version 2Διαδικασία 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

02

Αντικαθιστά τη δήλωση συμμόρφωσης από /  
Replaces Declaration of Conformity from

15.08.2022

Hanau, 08.08.2024

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.



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

Το ιατροτεχνολογικό προϊόν / *The medical device* **GLUMA 2Bond**

Αριθμός έκδοσης / *Version number* **03**

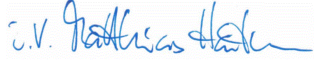
Αντικαθιστά το Παράρτημα από / *Replaces Annex from* **23.11.2022**

Αυτός ο κατάλογος προϊόντων ισχύει για την έκδοση δήλωσης συμμόρφωσης / *This article list is valid for the declaration of conformity version* **02**

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hanau, 08.08.2024

Τόπος, ημερομηνία / *Place, date*

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

Όνοματεπώνυμο και τίτλος / *Name and function*

**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-00007705**Izjavljujemo pod punom odgovornošću da / We declare under our sole responsibility that**medicinski proizvod / *the medical device***GLUMA 2Bond**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*

Q010101

šifra GMDN / *GMDN code*

34782

šifra UMDNS / *UMDNS code*

10-034

osnovni UDI-DI / *Basic UDI-DI*

++J0141103BA01010104bL8

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*Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod **GLUMA 2Bond**, verzija 2  
*Further Applied standards see Technical Documentation of Product **GLUMA 2Bond**, 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*

02

Zamjenjuje Izjavu o usklađenosti od /  
*Replaces Declaration of Conformity from*

15.08.2022

Hanau, 08.08.2024

i.V. Dr. Matthias Hartmann   
Head of Global Quality, Regulatory & Scientific Services  
**Kulzer GmbH**Mjesto, datum / *Place, date*Ime i funkcija / *Name and function*Ova Izjava o usklađenosti valjana je 2 godine u odnosu na dokumente o izdanju za odgovarajuće serije proizvedenih umedicinskih proizvoda. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*



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

Medicinski proizvod / **GLUMA 2Bond**  
*The medical device*


Broj verzije / **03**  
*Version number*

Zamjenjuje Dodatak od / **23.11.2022**  
*Replaces Annex from*

Ovaj popis artikala valjan je za verziju izjave  
u sukladnosti / **02**  
*This article list is valid for the  
declaration of conformity version*

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hanau, 08.08.2024

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 2Bond**

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  
++J0141103BA01010104bL8

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 2Bond**, 2. verzió  
Further Applied standards see Technical Documentation of  
Product **GLUMA 2Bond**, Version 2

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

02

Felváltja a megfelelőségi nyilatkozatot ettől /  
Replaces Declaration of Conformity from

15.08.2022

Hanau, 08.08.2024

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.

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

Az orvostechnikai eszköz / **GLUMA 2Bond**  
*The medical device*

Verziószám / **03**  
*Version number*


Felváltja a mellékletet ettől / **23.11.2022**  
*Replaces Annex from*

Ez a tételista a megfelelőségi nyilatkozat **02**  
következő verziójához érvényes / *This article*  
*list is valid for the declaration of conformity*  
*version*

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hanau, 08.08.2024

Hely, dátum / *Place, date*

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

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-00007705

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

medicinos prietaisas / *the medical device*

**GLUMA 2Bond**

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  
 ++J0141103BA01010104bL8

klasės / *of class*

Ila

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 2Bond**, techninėje dokumentacijoje, 2 versijoje *Further Applied standards see Technical Documentation of Product GLUMA 2Bond, 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

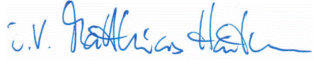
Versijos numeris / *Version number*

02

Pakeičia atitikties deklaraciją nuo /  
*Replaces Declaration of Conformity from*

15.08.2022

Hanau, 08.08.2024

  
 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.*



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

Medicinos prietaisas / **GLUMA 2Bond**  
*The medical device*

Versijos numeris / **03**  
*Version number*

Pakeičia Priedą nuo / **23.11.2022**  
*Replaces Annex from*

Šis straipsnių sąrašas tinka atitikties **02**  
deklaracijai, kurios versija yra / *This article*  
*list is valid for the declaration of conformity*  
*version*

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hanau, 08.08.2024

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*

## 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 2Bond**

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  
 ++J0141103BA01010104bL8

klasy / *of class*

Ila

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 2Bond**, wersja 2  
*Further Applied standards see Technical Documentation of  
 Product GLUMA 2Bond, 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*

02

Zastępuje Deklarację zgodności z /  
*Replaces Declaration of Conformity from*

15.08.2022

Hanau, 08.08.2024

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 2Bond**  
*The medical device*

Numer wersji / **03**  
*Version number*


Zastępuje załącznik z dnia / **23.11.2022**  
*Replaces Annex from*

Poniższa lista artykułów obowiązuje dla **02**  
następujących wersji deklaracji zgodności /  
*This article list is valid for the declaration of*  
*conformity version*

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hanau, 08.08.2024

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*

**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-00007705

**Mēs vienīgi uz savu atbildību deklarējam, ka / We declare under our sole responsibility that**medicīniskā ierīce / *the medical device***GLUMA 2Bond**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*

Q010101

GMDN kods / *GMDN code*

34782

UMDNS kods / *UMDNS code*

10-034

Pamata UDI-DI / *Basic UDI-DI*

++J0141103BA01010104bL8

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*Citus izmantotos standartus skatiet tehniskajā dokumentācijā par produktu **GLUMA 2Bond**, 2. versija  
*Further Applied standards see Technical Documentation of Product GLUMA 2Bond, 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*

02

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

15.08.2022

Hānava 08.08.2024

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.*



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

Medicīniskā ierīce / *The medical device* **GLUMA 2Bond**


Versijas numurs / *Version number* **03**

Aizstāj pielikumu, kas datēts ar / *Replaces Annex from* **23.11.2022**

Šis izstrādājumu saraksts ir derīgs šādai atbilstības deklarācijas versijai / *This article list is valid for the declaration of conformity version* **02**

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hānava 08.08.2024

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*

## 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-00007705

Declarăm pe propria răspundere că / *We declare under our sole responsibility that*  
 dispozitivul medical / *the medical device*

**GLUMA 2Bond**

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  
 ++J0141103BA01010104bL8

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 2Bond**, Versiunea 2  
*Further Applied standards see Technical Documentation of  
 Product GLUMA 2Bond, 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*

02

Înlocuiește Declarația de conformitate din /  
*Replaces Declaration of Conformity from*

15.08.2022

Hanau, 08.08.2024

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 2Bond**  
*The medical device*

Număr versiune / **03**  
*Version number*

Înlocuiește Anexa de la / **23.11.2022**  
*Replaces Annex from*

Această listă de articole este valabilă pentru **02**  
declarația de conformitate versiunea / *This*  
*article list is valid for the declaration of*  
*conformity version*

<b>UDI-DI</b>	<b>Article number</b>	<b>Article name</b>
+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hanau, 08.08.2024

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

Loc, dată / *Place, date*

Nume și funcție / *Name and function*

## 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-00007705

**Z izključno odgovornostjo izjavljamo, da / *We declare under our sole responsibility that***  
 medicinski pripomoček / *the medical device* **GLUMA 2Bond**

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* Q010101  
 Koda GMDN / *GMDN code* 34782  
 Koda UMDNS / *UMDNS code* 10-034  
 Osnovni UDI-DI / *Basic UDI-DI* ++J0141103BA01010104bL8

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 2Bond**, različica 2  
*Further Applied standards see Technical Documentation of Product **GLUMA 2Bond**, 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* 02

Nadomešča Izjavo o skladnosti z dne / *Replaces Declaration of Conformity from* 15.08.2022

Hanau, 08.08.2024

  
 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 2Bond**  
*The medical device*

Številka različice / **03**  
*Version number*


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+J014660409720	66040972	GLUMA 2Bond Bottle Refill
+J014660409710	66040971	GLUMA 2Bond Bottle Value Pack
+J014660961100	66096110	PROC GLUMA 2BOND KIT 1X4ML

Hanau, 08.08.2024

Kraj, datum / *Place, date*

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