

**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*
**Charisma Diamond**

 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  
 35870  
 16-724  
 ++J0141103COMP010103b7W

 der Klasse / *of class*

IIa

 nach Regel / *according to rule*

 8-1, 19-3 nach Anhang VIII der Medizinprodukte-Verordnung,  
 2017/745 / *according to Annex VIII of Medical Device Regulation  
 2017/745*
**allen Anforderungen der Medizinprodukte-Verordnung 2017/745 entspricht, die anwendbar sind /  
 meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.**

 Angewandte harmonisierte Normen, nationale  
 Normen oder andere normative Dokumente /  
*Applied harmonised standards, national standards  
 or other normative documents*

 EN ISO 4049 - Dentistry- Polymer-based restorative materials  
 Weitere angewandte Normen siehe Version 03 der Technischen  
 Dokumentation von Product Charisma Diamond / *Further Applied  
 standards see Technical Documentation of Product Charisma  
 Diamond, Version 03*

 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*

03

 Ersetzt Konformitätserklärung vom /  
*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**

 Ort, Datum / *Place, date*

 Name und Funktion / *Name and function*

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

## Artikelliste / List of Articles

### Anhang zur Konformitätserklärung / Annex to declaration of conformity

das Medizinprodukt /  
for the medical device

**Charisma Diamond**

Versionsnummer Artikelliste /  
Version number article list

04

Ersetzt Artikelliste vom /  
Replaces article list from

08.08.2024

Diese Artikelliste ist gültig für die Konformitätserklärung Version / 03  
This article list is valid for the declaration of conformity version

<b>UDI-DI / UDI-DI</b>	<b>Artikelnummer / Article number</b>	<b>Name / Name</b>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
+J014660439000	66043900	CHARISMA DIAMOND SYR REFILL 1X4G AM
+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
+J014660445110	66044511	CHARISMA DIAMOND SYR ROW REFILL 1X4G A2
+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
+J014660445160	66044516	CHARISMA DIAMOND SYR ROW REFILL 1X4G B2
+J014660445170	66044517	CHARISMA DIAMOND SYR ROW REFILL 1X4G B3
+J014660445180	66044518	CHARISMA DIAMOND SYR ROW REFILL 1X4G C2
+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3
+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL
+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM

+J014660445240	66044524	CHARISMA DIAMOND SYR ROW REFILL 1X4G OD
+J014660445250	66044525	CHARISMA DIAMOND SYR ROW REFILL 1X4G BL
+J014660445260	66044526	CHARISMA DIAMOND SYR ROW REFILL 1X4G BXL
+J014660445270	66044527	CHARISMA DIAMOND SYR ROW REFILL 1X4G OB
+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, 21.10.2024

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

**Charisma Diamond**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  
35870  
16-724  
++J0141103COMP010103b7W

от клас / of class

IIa

съгласно правило / according to rule

8-1, 19-3 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 documentsEN ISO 4049 - Dentistry- Polymer-based restorative materials  
Други приложени стандарти, вижте техническата  
документация на продукт Charisma Diamond Версия 03  
Further Applied standards see Technical Documentation of  
Product Charisma Diamond, Version 03Процедура 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

03

Заменя Декларация за съответствие от /  
Replaces Declaration of Conformity from

08.08.2024

Ханау, 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 / **Charisma Diamond**  
*The medical device*

Номер на версия / *Version number* 04

Заменя Приложението от / 08.08.2024  
*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*

<b>UDI-DI / UDI-DI</b>	<b>Номер на артикул / Article number</b>	<b>Наименование / Name</b>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
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+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
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+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3
+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL
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+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Ханау, 21.10.2024

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**Charisma Diamond**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 code  
Kód UMDNS / UMDNS code  
Základní UDI-DI / Basic UDI-DIQ010101  
35870  
16-724  
++J0141103COMP010103b7W

třídy / of class

IIa

podle pravidla / according to rule

8-1, 19-3 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  
documentsEN ISO 4049 - Dentistry- Polymer-based restorative materials  
Další použité normy najdete v technické dokumentaci k  
výrobku Charisma Diamond, verze 03  
Further Applied standards see Technical Documentation of  
Product Charisma Diamond, 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 IIIMedical 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 /  
The medical device

**Charisma Diamond**

Číslo verze / Version number

04

Nahrazuje přílohu ze dne /  
Replaces Annex from

08.08.2024

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

03

<b>UDI-DI / UDI-DI</b>	<b>Číslo zboží / Article number</b>	<b>Název / Name</b>
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+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, 21.10.2024

Místo, datum / Place, date

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

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

**Charisma Diamond**

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  
 35870  
 16-724  
 ++J0141103COMP010103b7W

klassil / of class

Ila

kooskõlas reegluga / according to rule

8-1, 19-3 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  
 Muud rakenduvaid standardeid vt tehnilistest  
 dokumentidest tootele Charisma Diamond, Version 03  
 Further Applied standards see Technical Documentation of  
 Product Charisma Diamond, 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>	<b>Charisma Diamond</b>
Versiooni number / <i>Version number</i>	04
Asendab lisa alates / <i>Replaces Annex from</i>	08.08.2024
See artiklite loend kehtib vastavusdeklaratsiooni versiooni kohta / <i>This article list is valid for the declaration of conformity version</i>	03

<b>UDI-DI / UDI-DI</b>	<b>Artikli number / Article number</b>	<b>Nimi / Name</b>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
+J014660439000	66043900	CHARISMA DIAMOND SYR REFILL 1X4G AM
+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
+J014660445110	66044511	CHARISMA DIAMOND SYR ROW REFILL 1X4G A2
+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
+J014660445160	66044516	CHARISMA DIAMOND SYR ROW REFILL 1X4G B2
+J014660445170	66044517	CHARISMA DIAMOND SYR ROW REFILL 1X4G B3
+J014660445180	66044518	CHARISMA DIAMOND SYR ROW REFILL 1X4G C2

+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3
+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL
+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM
+J014660445240	66044524	CHARISMA DIAMOND SYR ROW REFILL 1X4G OD
+J014660445250	66044525	CHARISMA DIAMOND SYR ROW REFILL 1X4G BL
+J014660445260	66044526	CHARISMA DIAMOND SYR ROW REFILL 1X4G BXL
+J014660445270	66044527	CHARISMA DIAMOND SYR ROW REFILL 1X4G OB
+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

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

## 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-00007705

**Declaramos bajo nuestra exclusiva responsabilidad que / We declare under our sole responsibility that**  
 el producto sanitario / *the medical device*

**Charisma Diamond**

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  
 35870  
 16-724  
 ++J0141103COMP010103b7W

de la clase / *of class*

Ila

de acuerdo con la norma / *according to rule*

8-1, 19-3 de acuerdo con el Anexo VIII del Reglamento sobre  
 productos sanitarios 2017/745 / *according to Annex VIII of Medical*  
*Device Regulation 2017/745*

**cumple todas las disposiciones del Reglamento sobre productos sanitarios 2017/745 que se le aplican. / meets all**  
**the provisions of the Medical Device Regulation 2017/745 which apply to it.**

Normas armonizadas, normas nacionales u otros  
 documentos normativos que se aplican / *Applied*  
*harmonised standards, national standards or other*  
*normative documents*

EN ISO 4049 - Dentistry– Polymer-based restorative materials  
 Para otras normas aplicadas consulte la documentación técnica del  
 producto Charisma Diamond, versión 03  
*Further Applied standards see Technical Documentation of*  
*Product Charisma Diamond, Version 03*

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*

03

Sustituye a la declaración de conformidad del /  
*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**

Lugar, fecha / *Place, date*

Nombre y cargo / *Name and function*

La presente declaración de conformidad tendrá una validez de 2 años según la documentación emitida para el correspondiente lote de productos fabricados. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

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

El producto sanitario / **Charisma Diamond**  
*The medical device*

Número de versión / *Version number* 04

Sustituye al Anexo del / 08.08.2024  
*Replaces Annex from*


Esta lista de artículos es válida para la 03  
 versión de la declaración de conformidad /  
*This article list is valid for the declaration of*  
*conformity version*

<b>UDI-DI / UDI-DI</b>	<b>Número de artículo / Article number</b>	<b>Nombre / Name</b>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
+J014660439000	66043900	CHARISMA DIAMOND SYR REFILL 1X4G AM
+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
+J014660445110	66044511	CHARISMA DIAMOND SYR ROW REFILL 1X4G A2
+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
+J014660445160	66044516	CHARISMA DIAMOND SYR ROW REFILL 1X4G B2
+J014660445170	66044517	CHARISMA DIAMOND SYR ROW REFILL 1X4G B3
+J014660445180	66044518	CHARISMA DIAMOND SYR ROW REFILL 1X4G C2
+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3

+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL
+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM
+J014660445240	66044524	CHARISMA DIAMOND SYR ROW REFILL 1X4G OD
+J014660445250	66044525	CHARISMA DIAMOND SYR ROW REFILL 1X4G BL
+J014660445260	66044526	CHARISMA DIAMOND SYR ROW REFILL 1X4G BXL
+J014660445270	66044527	CHARISMA DIAMOND SYR ROW REFILL 1X4G OB
+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, 21.10.2024

Lugar, fecha / Place, date

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

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Nombre y cargo / 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***Charisma Diamond**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  
35870  
16-724  
++J0141103COMP010103b7Wκλάσης / *of class*

IIa

σύμφωνα με τον κανόνα / *according to rule*8-1, 19-3 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 Charisma Diamond, έκδοση 03  
*Further Applied standards see Technical Documentation of  
Product Charisma Diamond, Version 03*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*

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 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* **Charisma Diamond**

Αριθμός έκδοσης / *Version number* 04

Αντικαθιστά το Παράρτημα από / *Replaces Annex from* 08.08.2024


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

UDI-DI / <i>UDI-DI</i>	Αριθμός είδους / <i>Article number</i>	Όνομα / <i>Name</i>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
+J014660439000	66043900	CHARISMA DIAMOND SYR REFILL 1X4G AM
+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
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+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
+J014660445160	66044516	CHARISMA DIAMOND SYR ROW REFILL 1X4G B2
+J014660445170	66044517	CHARISMA DIAMOND SYR ROW REFILL 1X4G B3
+J014660445180	66044518	CHARISMA DIAMOND SYR ROW REFILL 1X4G C2
+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3

+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL
+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM
+J014660445240	66044524	CHARISMA DIAMOND SYR ROW REFILL 1X4G OD
+J014660445250	66044525	CHARISMA DIAMOND SYR ROW REFILL 1X4G BL
+J014660445260	66044526	CHARISMA DIAMOND SYR ROW REFILL 1X4G BXL
+J014660445270	66044527	CHARISMA DIAMOND SYR ROW REFILL 1X4G OB
+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, 21.10.2024

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***Charisma Diamond**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*

35870

šifra UMDNS / *UMDNS code*

16-724

osnovni UDI-DI / *Basic UDI-DI*

++J0141103COMP010103b7W

klase / *of class*

IIa

u skladu s pravilom / *according to rule*8-1, 19-3 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 Charisma Diamond , verzija 03  
*Further Applied standards see Technical Documentation of Product Charisma Diamond, Version 03*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*

03

Zamjenjuje Izjavu o usklađenosti od /  
*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**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 / **Charisma Diamond**  
*The medical device*

Broj verzije / *Version number* 04

Zamjenjuje Dodatak od / 08.08.2024  
*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*

<b>UDI-DI / UDI-DI</b>	<b>Broj artikla / Article number</b>	<b>Naziv / Name</b>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
+J014660439000	66043900	CHARISMA DIAMOND SYR REFILL 1X4G AM
+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
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+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
+J014660445160	66044516	CHARISMA DIAMOND SYR ROW REFILL 1X4G B2
+J014660445170	66044517	CHARISMA DIAMOND SYR ROW REFILL 1X4G B3
+J014660445180	66044518	CHARISMA DIAMOND SYR ROW REFILL 1X4G C2
+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3



+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL
+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM
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+J014660445250	66044525	CHARISMA DIAMOND SYR ROW REFILL 1X4G BL
+J014660445260	66044526	CHARISMA DIAMOND SYR ROW REFILL 1X4G BXL
+J014660445270	66044527	CHARISMA DIAMOND SYR ROW REFILL 1X4G OB
+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
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+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, 21.10.2024

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-000007705Kizárólagos felelősségünkre kijelentjük, hogy / We declare under our sole responsibility that  
az orvostechikai eszköz / the medical device **Charisma Diamond**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-DIQ010101  
35870  
16-724  
++J0141103COMP010103b7W

osztálya / of class

IIa

a következő szabály szerint / according to rule

8-1, 19-3 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 documentsEN ISO 4049 - Dentistry- Polymer-based restorative materials  
További alkalmazott szabványokat lásd a műszaki dokumentációban,  
termék: Charisma Diamond, 03. verzió  
Further Applied standards see Technical Documentation of  
Product Charisma Diamond, Version 03Megfelelőségértékelési eljárás a következő szerint  
/ Conformity assessment procedure acc. toAz 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 / *The medical device* **Charisma Diamond**

Verziószám / *Version number* 04


Felváltja a mellékletet ettől / *Replaces Annex from* 08.08.2024

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

<b>UDI-DI / UDI-DI</b>	<b>Cikkszám / Article number</b>	<b>Név / Name</b>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
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+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
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+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
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+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
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+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
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+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3

+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL
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+J014660445250	66044525	CHARISMA DIAMOND SYR ROW REFILL 1X4G BL
+J014660445260	66044526	CHARISMA DIAMOND SYR ROW REFILL 1X4G BXL
+J014660445270	66044527	CHARISMA DIAMOND SYR ROW REFILL 1X4G OB
+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

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

**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*

**Charisma Diamond**

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  
35870  
16-724  
++J0141103COMP010103b7W

klasės / *of class*

Ila

pagal taisyklę / *according to rule*

8-1, 19-3 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 Charisma Diamond, techninėje dokumentacijoje, 03 versijoje  
*Further Applied standards see Technical Documentation of Product Charisma Diamond, 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 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 / **Charisma Diamond**  
*The medical device*

Versijos numeris / *Version number* 04


Pakeičia Priedą nuo / 08.08.2024  
*Replaces Annex from*

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

<b>UDI-DI / UDI-DI</b>	<b>Prekės numeris / Article number</b>	<b>Pavadinimas / Name</b>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
+J014660439000	66043900	CHARISMA DIAMOND SYR REFILL 1X4G AM
+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
+J014660445110	66044511	CHARISMA DIAMOND SYR ROW REFILL 1X4G A2
+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
+J014660445160	66044516	CHARISMA DIAMOND SYR ROW REFILL 1X4G B2
+J014660445170	66044517	CHARISMA DIAMOND SYR ROW REFILL 1X4G B3
+J014660445180	66044518	CHARISMA DIAMOND SYR ROW REFILL 1X4G C2
+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3
+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL
+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM
+J014660445240	66044524	CHARISMA DIAMOND SYR ROW REFILL 1X4G OD

+J014660445250	66044525	CHARISMA DIAMOND SYR ROW REFILL 1X4G BL
+J014660445260	66044526	CHARISMA DIAMOND SYR ROW REFILL 1X4G BXL
+J014660445270	66044527	CHARISMA DIAMOND SYR ROW REFILL 1X4G OB
+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, 21.10.2024

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

**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**Charisma Diamond**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-DIQ010101  
35870  
16-724  
++J0141103COMP010103b7W

klase / of class

IIa

saskaņā ar noteikumu / according to rule

8-1, 19-3 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  
documentsEN ISO 4049 - Dentistry- Polymer-based restorative materials  
Citus izmantotos standartus skatiet tehniskajā dokumentācijā par  
produktu Charisma Diamond, 03. versija  
Further Applied standards see Technical Documentation of  
Product Charisma Diamond, Version 03Atbilstības novērtēšanas procedūra saskaņā ar /  
Conformity assessment procedure acc. toMedicīnisko 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 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 / <i>The medical device</i>	<b>Charisma Diamond</b>
Versijas numurs / <i>Version number</i>	04
Aizstāj pielikumu, kas datēts ar / <i>Replaces Annex from</i>	08.08.2024
Šis izstrādājumu saraksts ir derīgs šādai atbilstības deklarācijas versijai / <i>This article list is valid for the declaration of conformity version</i>	03

<b>UDI-DI / UDI-DI</b>	<b>Preces numurs / Article number</b>	<b>Nosaukums / Name</b>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
+J014660439000	66043900	CHARISMA DIAMOND SYR REFILL 1X4G AM
+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
+J014660445110	66044511	CHARISMA DIAMOND SYR ROW REFILL 1X4G A2
+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
+J014660445160	66044516	CHARISMA DIAMOND SYR ROW REFILL 1X4G B2
+J014660445170	66044517	CHARISMA DIAMOND SYR ROW REFILL 1X4G B3
+J014660445180	66044518	CHARISMA DIAMOND SYR ROW REFILL 1X4G C2
+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3

+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL
+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM
+J014660445240	66044524	CHARISMA DIAMOND SYR ROW REFILL 1X4G OD
+J014660445250	66044525	CHARISMA DIAMOND SYR ROW REFILL 1X4G BL
+J014660445260	66044526	CHARISMA DIAMOND SYR ROW REFILL 1X4G BXL
+J014660445270	66044527	CHARISMA DIAMOND SYR ROW REFILL 1X4G OB
+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hānava 21.10.2024

Vieta, datums / Place, date

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

---

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*

**Charisma Diamond**

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  
 35870  
 16-724  
 ++J0141103COMP010103b7W

klasy / *of class*

Ila

zgodnie z regułą / *according to rule*

8-1, 19-3 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 Charisma Diamond, wersja 03  
*Further Applied standards see Technical Documentation of  
 Product Charisma Diamond, 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 / <i>The medical device</i>	<b>Charisma Diamond</b>
Numer wersji / <i>Version number</i>	04
Zastępuje załącznik z dnia / <i>Replaces Annex from</i>	08.08.2024
Poniższa lista artykułów obowiązuje dla następujących wersji deklaracji zgodności / <i>This article list is valid for the declaration of conformity version</i>	03


UDI-DI / <i>UDI-DI</i>	Numer wyrobu / <i>Article number</i>	Nazwa / <i>Name</i>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
+J014660439000	66043900	CHARISMA DIAMOND SYR REFILL 1X4G AM
+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
+J014660445110	66044511	CHARISMA DIAMOND SYR ROW REFILL 1X4G A2
+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
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+J014660445180	66044518	CHARISMA DIAMOND SYR ROW REFILL 1X4G C2
+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3
+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL



+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM
+J014660445240	66044524	CHARISMA DIAMOND SYR ROW REFILL 1X4G OD
+J014660445250	66044525	CHARISMA DIAMOND SYR ROW REFILL 1X4G BL
+J014660445260	66044526	CHARISMA DIAMOND SYR ROW REFILL 1X4G BXL
+J014660445270	66044527	CHARISMA DIAMOND SYR ROW REFILL 1X4G OB
+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, 21.10.2024

Miejscowość, data / Place, date

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

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Imię i nazwisko, stanowisko / Name and function

## DECLARAÇÃO DE CONFORMIDADE / DECLARATION OF CONFORMITY

Nome e morada da empresa /  
 Name and address of the company

**Kulzer GmbH**  
 Leipziger Straße 2, 63450 Hanau  
 Alemanha / Germany  
 SRN: DE-MF-000007705

**Declaramos, sob nossa exclusiva responsabilidade, que / We declare under our sole responsibility that**  
 o dispositivo médico / the medical device

### Charisma Diamond

Nome, tipo ou modelo, número de lote ou de série,  
 possivelmente origem e quantidade de itens /  
 Name, type or model, batch or serial number,  
 possibly sources and number of items

Lista de artigos, ver Anexo / List of Articles see Annex

Código EMDN / EMDN-Code  
 Código GMDN / GMDN code  
 Código UMDNS / UMDNS code  
 UDI-DI básico / Basic UDI-DI

Q010101  
 35870  
 16-724  
 ++J0141103COMP010103b7W

da classe / of class

Ila

em conformidade com o regulamento / according to  
 rule

8-1, 19-3 em conformidade com o Anexo VIII do Regulamento  
 2017/745 relativo aos Dispositivos Médicos / according to Annex VIII  
 of Medical Device Regulation 2017/745

**cumpre todas as disposições aplicáveis do Regulamento 2017/745 relativo aos Dispositivos Médicos. /  
 meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.**

Normas harmonizadas aplicadas, normas nacionais  
 ou outros documentos normativos / Applied  
 harmonised standards, national standards or other  
 normative documents

EN ISO 4049 - Dentistry– Polymer-based restorative materials  
 Outras normas aplicadas, ver Documentação técnica do produto  
 Charisma Diamond, Versão 03  
 Further Applied standards see Technical Documentation of  
 Product Charisma Diamond, Version 03

Procedimento de avaliação da conformidade de  
 acordo com /  
 Conformity assessment procedure acc. to

Anexo IX do Regulamento 2017/745 relativo aos Dispositivos  
 Médicos, Capítulo I, secção 2 e 3 e Capítulo III

Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2  
 and 3 and Chapter III

Organismo notificado / Notified Body

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Alemanha

CE 0197

Número de registo / Registration number:

HZ 1198082-1

Número de versão / Version number

03

Substitui a Declaração de Conformidade de /  
 Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

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



Local, data / Place, date

Nome e função / Name and function

A presente declaração de conformidade é válida durante 2 anos em associação aos documentos do respetivo lote de dispositivos produzidos. / This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.

**Lista de artigos / List of Articles**  
**Anexo / Annex: Declaração de Conformidade / Declaration of Conformity**

O dispositivo médico / **Charisma Diamond**  
*The medical device*

Número de versão / *Version number* 04

Substitui o Anexo de / 08.08.2024  
*Replaces Annex from*


A presente lista de artigos é válida para a 03  
 versão da declaração de conformidade / *This*  
*article list is valid for the declaration of*  
*conformity version*

<b>UDI-DI / UDI-DI</b>	<b>Número de artigo / Article number</b>	<b>Nome / Name</b>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
+J014660439000	66043900	CHARISMA DIAMOND SYR REFILL 1X4G AM
+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
+J014660445110	66044511	CHARISMA DIAMOND SYR ROW REFILL 1X4G A2
+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
+J014660445160	66044516	CHARISMA DIAMOND SYR ROW REFILL 1X4G B2
+J014660445170	66044517	CHARISMA DIAMOND SYR ROW REFILL 1X4G B3
+J014660445180	66044518	CHARISMA DIAMOND SYR ROW REFILL 1X4G C2
+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3

+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL
+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM
+J014660445240	66044524	CHARISMA DIAMOND SYR ROW REFILL 1X4G OD
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+J014660445260	66044526	CHARISMA DIAMOND SYR ROW REFILL 1X4G BXL
+J014660445270	66044527	CHARISMA DIAMOND SYR ROW REFILL 1X4G OB
+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, 21.10.2024

Local, data / Place, date

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

---

Nome e função / Name and function

## DECLARAȚIE DE CONFORMITATE / DECLARATION OF CONFORMITY

Numele și adresa companiei /  
*Name and address of the company*

**Kulzer GmbH**  
 Leipziger Straße 2, 63450 Hanau  
 Germania / Germany  
 SRN: DE-MF-00007705

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

dispozitivul medical / *the medical device*

**Charisma Diamond**

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  
 35870  
 16-724  
 ++J0141103COMP010103b7W

din clasa / *of class*

IIa

în conformitate cu regula / *according to rule*

8-1, 19-3 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  
 Charisma Diamond, Versiunea 03  
 Further Applied standards see *Technical Documentation of  
 Product Charisma Diamond, 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 / **Charisma Diamond**  
*The medical device*

Număr versiune / *Version number* 04


Înlocuiește Anexa de la / *Replaces Annex from* 08.08.2024

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

<b>UDI-DI / UDI-DI</b>	<b>Număr articol / Article number</b>	<b>Nume / Name</b>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
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+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
+J014660445110	66044511	CHARISMA DIAMOND SYR ROW REFILL 1X4G A2
+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
+J014660445160	66044516	CHARISMA DIAMOND SYR ROW REFILL 1X4G B2
+J014660445170	66044517	CHARISMA DIAMOND SYR ROW REFILL 1X4G B3
+J014660445180	66044518	CHARISMA DIAMOND SYR ROW REFILL 1X4G C2
+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3
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+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
+J014660445290	66044529	CHARISMA DIAMOND SYR ROW REFILL 1X4G AM
+J014660445300	66044530	CHARISMA DIAMOND SYR ROW REFILL 1X4G CO
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+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

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

**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***Charisma Diamond**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  
35870  
16-724  
++J0141103COMP010103b7Wrazreda / *of class*

IIa

v skladu s členom / *according to rule*8-1, 19-3, 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 Charisma Diamond, različica 03  
*Further Applied standards see Technical Documentation of Product Charisma Diamond, Version 03*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*

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 / **Charisma Diamond**  
*The medical device*

Številka različice / *Version number* 04

Nadomešča Prilogo z dne / 08.08.2024  
*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>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
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+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
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+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
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+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
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+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM
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+J014660445280	66044528	CHARISMA DIAMOND SYR ROW REFILL 1X4G CL
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+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

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

**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-00007705Vyhlasujeme na svoju výlučnú zodpovednosť, že / *We declare under our sole responsibility that*  
zdravotnícka pomôcka / *the medical device* **Charisma Diamond**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*

Q010101

Kód GMDN / *GMDN code*

35870

Kód UMDNS / *UMDNS code*

16-724

Základné identifikačné číslo UDI-DI / *Basic UDI-DI*

++J0141103COMP010103b7W

triedy / *of class*

IIa

podľa pravidla / *according to rule*8-1, 19-3 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.***Použitie 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  
03 k produktu Charisma Diamond  
*Further Applied standards see Technical Documentation of*  
*Product Charisma Diamond, 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 / **Charisma Diamond**  
*The medical device*

Číslo verzie / *Version number* 04

Nahrádza prílohu z / 08.08.2024  
*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 / <i>UDI-DI</i>	Číslo položky / <i>Article number</i>	Meno / <i>Name</i>
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
+J014660438850	66043885	CHARISMA DIAMOND SYR REFILL 1X4GR A3.5
+J014660438860	66043886	CHARISMA DIAMOND SYR REFILL 1X4GR A4
+J014660438870	66043887	CHARISMA DIAMOND SYR REFILL 1X4GR B1
+J014660438880	66043888	CHARISMA DIAMOND SYR REFILL 1X4GR B2
+J014660438890	66043889	CHARISMA DIAMOND SYR REFILL 1X4G B3
+J014660438900	66043890	CHARISMA DIAMOND SYR REFILL 1X4G C2
+J014660438910	66043891	CHARISMA DIAMOND SYR REFILL 1X4G C3
+J014660438920	66043892	CHARISMA DIAMOND SYR REFILL 1X4G D3
+J014660438930	66043893	CHARISMA DIAMOND SYR REFILL 1X4G OL
+J014660438940	66043894	CHARISMA DIAMOND SYR REFILL 1X4G OM
+J014660438950	66043895	CHARISMA DIAMOND SYR REFILL 1X4G OD
+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
+J014660438970	66043897	CHARISMA DIAMOND SYR REFILL 1X4G BXL
+J014660438980	66043898	CHARISMA DIAMOND SYR REFILL 1X4G OB
+J014660438990	66043899	CHARISMA DIAMOND SYR REFILL 1X4G CL
+J014660439000	66043900	CHARISMA DIAMOND SYR REFILL 1X4G AM
+J014660439010	66043901	CHARISMA DIAMOND SYR REFILL 1X4G CO
+J014660439020	66043902	CHARISMA DIAMOND SYR REFILL 1X4G YO
+J014660444960	66044496	CHARISMA DIAMOND SYR ROW REFILL 1X4G A1
+J014660445110	66044511	CHARISMA DIAMOND SYR ROW REFILL 1X4G A2
+J014660445120	66044512	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3
+J014660445130	66044513	CHARISMA DIAMOND SYR ROW REFILL 1X4G A3.5
+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
+J014660445160	66044516	CHARISMA DIAMOND SYR ROW REFILL 1X4G B2
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+J014660445190	66044519	CHARISMA DIAMOND SYR ROW REFILL 1X4G C3
+J014660445210	66044521	CHARISMA DIAMOND SYR ROW REFILL 1X4G D3
+J014660445220	66044522	CHARISMA DIAMOND SYR ROW REFILL 1X4G OL



+J014660445230	66044523	CHARISMA DIAMOND SYR ROW REFILL 1X4G OM
+J014660445240	66044524	CHARISMA DIAMOND SYR ROW REFILL 1X4G OD
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+J014660445310	66044531	CHARISMA DIAMOND SYR ROW REFILL 1X4G YO
+J014660871680	66087168	CHARISMA DIAMOND SYR ROW REFILL 1x4g ONE
+J014660871690	66087169	CHARISMA DIAMOND SYR REFILL 1x4g ONE
+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, 21.10.2024

Miesto, dátum / Place, date

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

Meno a funkcia / Name and function


**Abschlusszertifikat**

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Dokumentenseiten: 45	Signaturen: 30
Zertifikatsseiten: 1	Initialen: 0
Signatur mit Anleitung: Aktiviert	Umschlagelagersteller:
Umschlag-ID-Stempel: Aktiviert	Anette Stadtfeld
Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien	Leipziger Str. 2
	Hanau, Hessen 63450
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**Eintragsverfolgung**

Status: Original	Inhaber: Anette Stadtfeld	Standort: DocuSign
21.10.2024 10:57:08	Anette.Stadtfeld@kulzer-dental.com	

**Unterzeichnereignisse**

Unterzeichnereignisse	Signatur	Zeitstempel
Matthias Hartmann matthias.hartmann@kulzer-dental.com Head of Global Quality, Regulatory & Scientific Services Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	 Signaturübernahme: Hochgeladenes Signaturbild Mit IP-Adresse: 77.186.183.50	Gesendet: 21.10.2024 11:03:01 Eingesehen: 21.10.2024 11:16:36 Signiert: 21.10.2024 11:17:24

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Vor-Ort-Unterzeichner – Ereignisse	Signatur	Zeitstempel
<b>Bearbeiterversandereignisse</b>	<b>Status</b>	<b>Zeitstempel</b>
<b>Beauftragenzustellereignisse</b>	<b>Status</b>	<b>Zeitstempel</b>
<b>Vermittlerversandereignisse</b>	<b>Status</b>	<b>Zeitstempel</b>
<b>Zertifizierter Versand - Ereignisse</b>	<b>Status</b>	<b>Zeitstempel</b>
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Daniela Wienhold Daniela.Wienhold@kulzer-dental.com Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	<b>Kopiert</b>	Gesendet: 21.10.2024 11:03:02
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<b>Umschlagereignisse – Überblick</b>	<b>Status</b>	<b>Zeitstempel</b>
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Abgeschlossen	Sicherheitsprüfung ausgeführt	21.10.2024 11:17:24
<b>Zahlungen</b>	<b>Status</b>	<b>Zeitstempel</b>