

**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**Artikelliste siehe Anhang / *List of Articles see Annex*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*EMDN-Nummer / *EMDN-Code*

Q 010101

GMDN-Nummer / *GMDN code*

35870

UMDNS-Nummer / *UMDNS code*

16-724

Basis-UDI-DI / *Basic UDI-DI*

++J0141103COMP010103b7W

der Klasse / *of class*

IIa

nach Regel / *according to rule*8, 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 1 der Technischen
Dokumentation von Product Charisma Diamond / *Further Applied
standards see Technical Documentation of Product Charisma
Diamond, Version 1*Konformitätsbewertungsverfahren nach /
*Conformity assessment procedure acc. to*Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I,
Abschnitt 2 und 3 and Kapitel III*Medical Device Regulation 2017/745 Annex IX, Chapter I,
Section 2 and 3 and Chapter III*Benannte Stelle / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Germany

CE 0197

Registrierungsnr. / *Registration No.:*

HZ 1198082-1

Versionsnummer / *Version number*

01

Ersetzt Konformitätserklärung vom /
Replaces Declaration of Conformity from

24.02.2022

Hanau, Aug 15, 2022

i.V.

Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services**Kulzer GmbH**Ort, Datum / *Place, date*Name und Funktion / *Name and function*Diese Konformitätserklärung ist gültig für 2 Jahre in Verbindung mit den Freigabe-Dokumenten für die jeweilige Charge der
produzierten Medizinprodukte / *This statement of conformity is valid for 2 years in connection with the release documents for the
respective batch of produced devices.*

Artikelliste / List of Articles

Anhang zur Konformitätserklärung / Annex to declaration of conformity

das Medizinprodukt /
for the medical device

Charisma Diamond

Versionsnummer Artikelliste/
Version number article list

02

Ersetzt Artikelliste vom /
Replaces article list from

V01, 2022-03-24

Diese Artikelliste ist gültig für die Konformitätserklärung Version/ 01
This article list is valid for the declaration of conformity version

UDI-DI / UDI-DI	Artikelnummer / Article number	Name / Name
+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
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+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
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+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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, Nov 22, 2022

Ort, Datum / Place, date

i.V.

Dr. Matthias Hartmann

Head of Global Quality, Regulatory & Scientific Services

Kulzer GmbH

Name und Funktion / Name and function





KULZER
MITSUBI CHEMICALS GROUP

ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ / *DECLARATION OF CONFORMITY*

Име и адрес на фирмата /
Name and address of the company

Kulzer GmbH
Leipziger Straße 2, 63450 Hanau
Германия / Germany

SRN: DE-MF-000007705

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

медицинското изделие / *the medical device*

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 items*

Списък с артикули, вижте Приложението /
List of Articles see Annex

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

Q 010101
35870
16-724
++J0141103COMP010103b7W

от клас / *of class*

IIa

съгласно правило / *according to rule*

8, 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 documents*

EN ISO 4049 - Dentistry- Polymer-based restorative materials
Други приложени стандарти, вижте техническата
документация на продукт Charisma Diamond Версия 1
*Further Applied standards see Technical Documentation of
Product Charisma Diamond, Version 1*

Процедура за оценка на съответствието съгласно /
Conformity assessment procedure acc. to

Регламента за медицинските изделия 2017/745 Приложение
IX, глава I, раздел 2 и 3 и глава III

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

Нотифициран орган / *Notified Body*

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Германия

CE 0197

Регистрационен номер / *Registration number*

HZ 1198082-1

Номер на версия / *Version number*

1

Заменя Декларация за съответствие от /
Replaces Declaration of Conformity from

24.02.2022

Ханау, Aug 15, 2022

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

Charisma Diamond

Номер на версия / *Version number*

02

Заменя Приложението от /
Replaces Annex from

V01, 2022-02-24

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

01

UDI-DI / UDI-DI	Номер на артикул / Article number	Наименование / Name
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
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+J014660438960	66043896	CHARISMA DIAMOND SYR REFILL 1X4G BL
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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

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+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
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+J014660871730	66087173	CHARISMA DIAMOND SYR SAMPLE KIT 1x1g ONE
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

M.V. Hartmann

Ханау, Nov 22, 2022

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


KULZER
 MITSUBI CHEMICALS GROUP

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 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

 Q 010101
 35870
 16-724
 ++J0141103COMP010103b7W

třídy / of class

IIa

podle pravidla / according to rule

 8, 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
 documents

 EN ISO 4049 - Dentistry- Polymer-based restorative materials
 Další použité normy najdete v technické dokumentaci k
 výrobku Charisma Diamond, verze 1
 Further Applied standards see Technical Documentation of
 Product Charisma Diamond, Version 1

 Procedura posouzení shody podle /
 Conformity assessment procedure acc. to

 nařízení 2017/745 o zdravotnických prostředcích, příloha IX,
 kapitola I, oddíl 2 a 3 a kapitola III

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

Notifikovaná osoba / Notified Body

 TÜV Rheinland LGA Products GmbH
 Tillystrasse 2
 90431 Nürnberg / Německo

CE 0197

Registrační číslo / Registration number:

HZ 1198082-1

Číslo verze / Version number

01

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

24.02.2022

Hanau, Aug 15, 2022

i.V.

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

Místo, datum / Place, date

Jméno a funkce / Name and function

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



Seznam položek / List of Articles

Příloha / Annex: Prohlášení o shodě / Declaration of Conformity

Zdravotnický prostředek /
The medical device

Charisma Diamond

Číslo verze / Version number

02

Nahrazuje přílohu ze dne /
Replaces Annex from

V01, 2022-02-24

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

01

UDI-DI / UDI-DI	Číslo zboží / Article number	Název / Name
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
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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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, Nov 22, 2022

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

Místo, datum / Place, date

Jméno a funkce / Name and function

**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

Q 010101
35870
16-724
++J0141103COMP010103b7W

klassil / of class

Ila

kooskõlas reegluga / according to rule

8, 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
Muid rakenduvaid standardeid vt tehnilistest
dokumentidest tootele Charisma Diamond, Version 1
Further Applied standards see Technical Documentation of
Product Charisma Diamond, Version 1

Vastavushindamismenetlus vastavalt /
Conformity assessment procedure acc. to

meditsiiniseadmete määruse 2017/745 IX. lisa, I. peatükk, 2. ja 3.
jaotis ning III. peatükk

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

Teavitatud asutus / Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Saksamaa

CE 0197

Registreerimisnumber / Registration number:

HZ 1198082-1

Versiooni number / Version number

01

Asendab vastavusdeklaratsiooni alates /
Replaces Declaration of Conformity from

24.02.2022

Hanau, Aug 15, 2022

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 /
The medical device

Charisma Diamond

Versiooni number / Version number

02

Asendab lisa alates /
Replaces Annex from

V01, 2022-02-24

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

01

UDI-DI / UDI-DI	Artikli number / Article number	Nimi / Name
+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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR



Hanau, Nov 22, 2022

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-000007705

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*

Q 010101
 35870
 16-724
 ++J0141103COMP010103b7W

de la clase / *of class*

Ila

de acuerdo con la norma / *according to rule*

8, 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 1
Further Applied standards see Technical Documentation of
Product Charisma Diamond, Version 1

Procedimiento de evaluación de la conformidad de
 acuerdo con /
Conformity assessment procedure acc. to

Reglamento sobre productos sanitarios 2017/745 Anexo IX,
 Capítulo I, Secciones 2 y 3 y Capítulo III
Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2
and 3 and Chapter III

Organismo notificado / *Notified Body*

TÜV Rheinland LGA Products GmbH
 Tillystrasse 2
 90431 Nürnberg / Alemania

CE 0197

Número de registro / *Registration number:*

HZ 1198082-1

Número de versión / *Version number*

01

Sustituye a la declaración de conformidad del /
Replaces Declaration of Conformity from

24.02.2022

Hanau, Aug 15, 2022


 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* 02

Sustituye al Anexo del / V01, 2022-03-03
Replaces Annex from

Esta lista de artículos es válida para la 01
 versión de la declaración de conformidad /
This article list is valid for the declaration of
conformity version

UDI-DI / UDI-DI	Número de artículo / Article number	Nombre / Name
+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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR



Hanau, Nov 22, 2022

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

Lugar, fecha / Place, date

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*Q 010101
35870
16-724
++J0141103COMP010103b7Wκλάσης / *of class*

IIa

σύμφωνα με τον κανόνα / *according to rule*8, 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 1
*Further Applied standards see Technical Documentation of
Product Charisma Diamond, Version 1*Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με
/ *Conformity assessment procedure acc. to*Κανονισμός 2017/745 για τα ιατροτεχνολογικά προϊόντα,
Παράρτημα IX, Κεφάλαιο I, Τμήμα 2 και 3, και Κεφάλαιο III
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section
2 and 3 and Chapter III*Κοινοποιημένος οργανισμός / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Γερμανία

CE 0197

Αριθμός καταχώρησης / *Registration number:*

HZ 1198082-1

Αριθμός έκδοσης / *Version number*

01

Αντικαθιστά τη δήλωση συμμόρφωσης από /
Replaces Declaration of Conformity from

24.02.2022

Hanau, Aug 15, 2022

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbHΤόπος, ημερομηνία / *Place,
date*Ονοματεπώνυμο και τίτλος / *Name and function*Αυτή η δήλωση συμμόρφωσης ισχύει για 2 χρόνια σε σχέση με τα έγγραφα κυκλοφορίας για την αντίστοιχη παρτίδα των
παραγόμενων προϊόντων. / *This statement of conformity is valid for 2 years in connection with the release documents for the
respective batch of produced devices.*

Κατάλογος ειδών / *List of Articles*

Παράρτημα / *Annex: Δήλωση συμμόρφωσης / Declaration of Conformity*

Το ιατροτεχνολογικό προϊόν /
The medical device

Charisma Diamond

Αριθμός έκδοσης / *Version number*

02

Αντικαθιστά το Παράρτημα από /
Replaces Annex from

V01, 2022-02-24

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

01

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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, Nov 22, 2022

Τόπος, ημερομηνία / *Place,*
date



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

Ονοματεπώνυμο και τίτλος / *Name and function*

**MEGFELELŐSÉGI NYILATKOZAT / DECLARATION OF CONFORMITY**

A vállalat neve és címe /
Name and address of the company

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

Kizárólagos felelősségünkre kijelentjük, hogy / We declare under our sole responsibility that
az orvostechnikai eszköz / the medical device **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-DI

Q 010101
35870
16-724
++J0141103COMP010103b7W

osztálya / of class

Ila

a következő szabály szerint / according to rule

8, 19-3 az orvostechnikai eszközökről szóló 2017/745 rendelet VIII.
melléklete szerint / according to Annex VIII of Medical Device
Regulation 2017/745

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

Alkalmazott harmonizált szabványok, nemzeti
szabványok vagy más normatív dokumentumok /
Applied harmonised standards, national standards
or other normative documents

EN ISO 4049 - Dentistry- Polymer-based restorative materials
További alkalmazott szabványokat lásd a műszaki dokumentációban,
termék: Charisma Diamond, 1. verzió
Further Applied standards see Technical Documentation of
Product Charisma Diamond, Version 1

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

Az orvostechnikai eszközökről szóló, 2017/745 rendelet IX. függeléke,
az I. fejezet 2. és 3. szakasza, és a III. fejezet

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

Bejelentett szervezet / Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Németország

CE 0197

Regisztrációs szám / Registration number:

HZ 1198082-1

Verziószám / Version number

01

Felváltja a megfelelőségi nyilatkozatot ettől /
Replaces Declaration of Conformity from

24.02.2022

Hanau, Aug 15, 2022

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 orvostechikai eszköz /
The medical device

Charisma Diamond

Verziószám / *Version number*

02

Felváltja a mellékletet ettől /
Replaces Annex from

V01, 2022-02-24

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

01

UDI-DI / UDI-DI	Cikkszám / Article number	Név / Name
+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
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+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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR



Hanau, Nov 22, 2022

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

Hely, dátum / Place, date

Név és funkció / 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-000007705

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

Q 010101

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, 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 1
*Further Applied standards see Technical Documentation of Product Charisma Diamond, Version 1*Postupak procjene usklađenosti prema /
Conformity assessment procedure acc. to

Prilog IX Uredbi 2017/745 o medicinskim proizvodima, Poglavlje I, Odjeljak 2 i 3 te Poglavlje III

*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*Obaviješteno tijelo / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Njemačka

CE 0197

Registracijski broj / *Registration number*

HZ 1198082-1

Broj verzije / *Version number*

01

Zamjenjuje Izjavu o usklađenosti od /
Replaces Declaration of Conformity from

24.02.2022

Hanau, Aug 15, 2022

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbHMjesto, 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 /
The medical device

Charisma Diamond

Broj verzije / *Version number*

02

Zamjenjuje Dodatak od /
Replaces Annex from

V01, 2022-03-03

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

01

UDI-DI / UDI-DI	Broj artikla / Article number	Naziv / Name
+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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, Nov 22, 2022

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

Mjesto, datum / Place, date

Ime i funkcija / 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-000007705

Prisiimdami visą atsakomybę pareiškiame, kad / We declare under our sole responsibility thatmedicinos prietaisais / *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*Q 010101
35870
16-724
++J0141103COMP010103b7Wklasės / *of class*

IIa

pagal taisyklę / *according to rule*8, 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, 1
versijoje
*Further Applied standards see Technical Documentation of
Product Charisma Diamond, Version 1]*]Atitikties patvirtinimo procedūra pagal /
*Conformity assessment procedure acc. to*Medicinos priemonių reglamento 2017/745 IX priedas, I skyrius, 2 ir
3 straipsniai bei III skyrius*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section
2 and 3 and Chapter III*Notifikuotoji įstaiga / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Vokietija

CE 0197

Registracijos numeris / *Registration number:*

HZ 1198082-1

Versijos numeris / *Version number*

01

Pakeičia atitikties deklaraciją nuo /
Replaces Declaration of Conformity from

24.02.2022

Hanau, Aug 15, 2022

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbHVieta, data / *Place, date*Vardas, pavardė ir pareigos / *Name and function*

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

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

Medicinos prietaisas /
The medical device

Charisma Diamond

Versijos numeris / *Version number*

02

Pakeičia Priedą nuo /
Replaces Annex from

V01, 2022-02-24

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

01

UDI-DI / UDI-DI	Prekės numeris / Article number	Pavadinimas / Name
+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
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+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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, Nov 22, 2022

Vieta, data / Place, date

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

Vardas, pavardė ir pareigos / Name and function

**ATBILSTĪBAS DEKLARĀCIJA / DECLARATION OF CONFORMITY**Uzņēmuma nosaukums un adrese /
*Name and address of the company***Kulzer GmbH**
Leipziger Straße 2, 63450 Hanau
Vācija / Germany

SRN: DE-MF-000007705

Mēs vienīgi uz savu atbildību deklarējam, ka / We declare under our sole responsibility thatmedicīniskā 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-DI*Q 010101
35870
16-724
++J0141103COMP010103b7Wklase / *of class*

IIa

saskaņā ar noteikumu / *according to rule*8, 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
documents*EN ISO 4049 - Dentistry- Polymer-based restorative materials
Citus izmantotos standartus skatiet tehniskajā dokumentācijā par
produktu Charisma Diamond, 1. versija
*Further Applied standards see Technical Documentation of
Product Charisma Diamond, Version 1*Atbilstības novērtēšanas procedūra saskaņā ar /
*Conformity assessment procedure acc. to*Medicīnisko ierīču regulas 2017/745 IX pielikumu, I nodaļu, 2. un
3. iedaļu un III nodaļu*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section
2 and 3 and Chapter III*Pilnvarotā iestāde / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg/Vācija

CE 0197

Reģistrācijas numurs / *Registration number:*

HZ 1198082-1

Versijas numurs / *Version number*

01

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

24.02.2022

Hānava Aug 15, 2022

v.i. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbHVieta, datums / *Place, date*Vārds, uzvārds un amats / *Name and function*

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



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

Medicīniskā ierīce /
The medical device

Charisma Diamond

Versijas numurs / Version number

02

Aizstāj pielikumu, kas datēts ar /
Replaces Annex from

V01, 2022-02-24

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

01

UDI-DI / UDI-DI	Preces numurs / Article number	Nosaukums / Name
+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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hānava Nov 22, 2022

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

Vieta, datums / Place, date

Vārds, uzvārds un amats / Name and function

**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

Q 010101
35870
16-724
++J0141103COMP010103b7W

klasy / of class

Ila

zgodnie z regułą / according to rule

8, 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 1
Further Applied standards see Technical Documentation of
Product Charisma Diamond, Version 1

Procedura oceny zgodności wg. /
Conformity assessment procedure acc. to

Rozporządzenie 2017/745 w sprawie wyrobów medycznych,
załącznik IX, rozdział I, sekcja 2 i 3 oraz rozdział III
Medical Device Regulation 2017/745 Annex IX, Chapter I, Section
2 and 3 and Chapter III

Jednostka notyfikowana / Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg/Niemcy

CE 0197

Numer rejestracyjny / Registration number:

HZ 1198082-1

Numer wersji / Version number

01

Zastępuje Deklarację zgodności z /
Replaces Declaration of Conformity from

24.02.2022

Hanau, Aug 15, 2022

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

Miejscowość, data / Place, date

Imię i nazwisko, stanowisko / Name and function

Niniejsze deklaracja zgodności jest ważna przez 2 lata w połączeniu z dokumentami zwolnienia odpowiedniej partii
wyprodukowanych wyrobów / This statement of conformity is valid for 2 years in connection with the release documents for the
respective batch of produced devices

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

Wyrób medyczny /
The medical device

Charisma Diamond

Numer wersji / *Version number*

02

Zastępuje załącznik z dnia /
Replaces Annex from

V01, 2022-02-24

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

01

UDI-DI / UDI-DI	Numer wyrobu / Article number	Nazwa / Name
+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
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+J014660445140	66044514	CHARISMA DIAMOND SYR ROW REFILL 1X4G A4
+J014660445150	66044515	CHARISMA DIAMOND SYR ROW REFILL 1X4G B1
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+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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, Nov 22, 2022

Miejscowość, data / Place, date



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

Imię i nazwisko, stanowisko / Name and function

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*

Q 010101
35870
16-724
++J0141103COMP010103b7W

da classe / *of class*

Ila

em conformidade com o regulamento / *according to*
rule

8, 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 1
Further Applied standards see Technical Documentation of
Product Charisma Diamond, Version 1

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

Anexo IX do Regulamento 2017/745 relativo aos Dispositivos
Médicos, Capítulo I, secção 2 e 3 e Capítulo III
Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2
and 3 and Chapter III

Organismo notificado / *Notified Body*

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Alemanha

CE 0197

Número de registo / *Registration number:*

HZ 1198082-1

Número de versão / *Version number*

01

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

24.02.2022

Hanau, Aug 15, 2022

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 /
The medical device

Charisma Diamond

Número de versão / *Version number*

02

Substitui o Anexo de /
Replaces Annex from

N/A

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

01

UDI-DI / UDI-DI	Número de artigo / Article number	Nome / Name
+J014660438820	66043882	CHARISMA DIAMOND SYR REFILL 1X4GR A1
+J014660438830	66043883	CHARISMA DIAMOND SYR REFILL 1X4GR A2
+J014660438840	66043884	CHARISMA DIAMOND SYR REFILL 1X4GR A3
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+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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR



Hanau, Nov 22, 2022

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

Local, data / Place, date

Nome e função / Name and function

**DECLARAȚIE DE CONFORMITATE / DECLARATION OF CONFORMITY**

Numele și adresa companiei /
Name and address of the company

Kulzer GmbH
Leipziger Straße 2, 63450 Hanau
Germania / Germany

SRN: DE-MF-000007705

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

dispozitivul medical / *the medical device*

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*

Q 010101
35870
16-724
++J0141103COMP010103b7W

din clasa / *of class*

IIa

în conformitate cu regula / *according to rule*

8, 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 1
*Further Applied standards see Technical Documentation of
Product Charisma Diamond, Version 1*

Procedură de evaluare a conformității în conf. cu /
Conformity assessment procedure acc. to

Regulamentul privind dispozitivele medicale 2017/745, Anexa IX,
Capitolul I, Secțiunile 2 și 3, și Capitolul III
*Medical Device Regulation 2017/745 Annex IX, Chapter I,
Section 2 and 3 and Chapter III*

Organism notificat / *Notified Body*

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Germany

CE 0197

Numărul de înregistrare / *Registration number*

HZ 1198082-1

Număr versiune / *Version number*

01

Înlocuiește Declarația de conformitate din /
Replaces Declaration of Conformity from

24.02.2022

Hanau, Aug 15, 2022

i.V.

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

Loc, dată / *Place, date*

Nume și funcție / *Name and function*

Prezenta declarație de conformitate este valabilă timp de 2 ani împreună cu documentele de autorizare pentru respectivul lot de
dispozitive produse / *This statement of conformity is valid for 2 years in connection with the release documents for the
respective batch of produced devices.*



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

Dispozitivul medical /
The medical device

Charisma Diamond

Număr versiune / *Version number*

02

Înlocuiește Anexa de la /
Replaces Annex from

V01, 2022-02-24

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

01

UDI-DI / UDI-DI	Număr articol / Article number	Nume / Name
+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
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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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR



Hanau, Nov 22, 2022

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

Loc, dată / Place, date

Nume și funcție / Name and function

**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 thatmedicinski 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*Q 010101
35870
16-724
++J0141103COMP010103b7Wrazreda / *of class*

IIa

v skladu s členom / *according to rule*8, 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 1
*Further Applied standards see Technical Documentation of Product Charisma Diamond, Version 1*Postopek ugotavljanja skladnosti v skladu z /
*Conformity assessment procedure acc. to*Uredbo o medicinskih pripomočkih 2017/745, Priloga IX, poglavje I, oddelka 2 in 3, poglavje III
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*Priglašeni organ / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg/Nemčija

CE 0197

Registrska številka / *Registration number*

HZ 1198082-1

Številka različice / *Version number*

01

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

24.02.2022

Hanau, Aug 15, 2022

zastopnica Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbHKraj, 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 /
The medical device

Charisma Diamond

Številka različice / *Version number*

02

Nadomešča Prilogo z dne /
Replaces Annex from

V01, 2022-02-24

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

01

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
+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
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+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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, Nov 22, 2022

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

Kraj, datum / Place, date

Ime in položaj / Name and function

**VYHLÁSENIE O ZHODE / DECLARATION OF CONFORMITY**

Názov a adresa spoločnosti /
Name and address of the company

Kulzer GmbH
Leipziger Straße 2, 63450 Hanau
Nemecko / Germany

SRN: DE-MF-000007705

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

zdravotnícka pomôcka / the medical device

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

Q 010101

Kód GMDN / GMDN code

35870

Kód UMDNS / UMDNS code

16-724

Základné identifikačné číslo UDI-DI / Basic UDI-DI

++J0141103COMP010103b7W

triedy / of class

Ila

podľa pravidiel / according to rule

8, 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.

Použité harmonizované normy, národné normy alebo iné normatívne dokumenty / Applied harmonised standards, national standards or other normative documents

EN ISO 4049 - Dentistry- Polymer-based restorative materials
Ďalšie použité normy nájdete v technickej dokumentácii verzie 1 k produktu Charisma Diamond
Further Applied standards see Technical Documentation of Product Charisma Diamond, Version 1

Postup posúdenia zhody podľa /
Conformity assessment procedure acc. to

prílohy IX k nariadeniu 2017/745 o zdravotníckych pomôckach, kapitola I, časť 2 a 3 a kapitola III

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

Notifikovaný orgán / Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Nemecko

CE 0197

Registračné číslo / Registration number:

HZ 1198082-1

Číslo verzie / Version number

01

Nahrádza vyhlásenie o zhode z /
Replaces Declaration of Conformity from

24.02.2022

Hanau, Aug 15, 2022

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

Miesto, dátum / Place, date

Meno a funkcia / Name and function

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



Zoznam položiek / *List of Articles*

Príloha / *Annex: Vyhlásenie o zhode / Declaration of Conformity*

Zdravotnícka pomôcka /
The medical device

Charisma Diamond

Číslo verzie / *Version number*

02

Nahrádza prílohu z /
Replaces Annex from

V01, 2022-02-24

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

01

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
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+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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+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
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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
+J014660438640	66043864	CHARISMA DIAMOND BASIC KIT
+J014660960930	66096093	PROC CHARISMA DIAMOND ONE KIT 2X4G SYR
+J014660961050	66096105	PROC CHARISMA DIAMOND 10X4G SYR

Hanau, Nov 22, 2022

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

Miesto, dátum / Place, date

Meno a funkcia / Name and function

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Umschlag-ID: 9810D10822924D57BBBF3FBAD8E95312

Status: Abgeschlossen

Betreff: Mit DocuSign abschließen: Charisma Diamond Annex komplett.pdf

Quellumschlag:

Dokumentenseiten: 30

Signaturen: 15

Umschlagsteller:

Zertifikatsseiten: 4

Initialen: 0

Anette Stadtfeld

Signatur mit Anleitung: Aktiviert

Leipziger Str. 2

Umschlag-ID-Stempel: Aktiviert

Hanau, Hessen 63450

Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien

Anette.Stadtfeld@kulzer-dental.com

IP-Adresse: 89.246.249.146

Eintragsverfolgung

Status: Original

Inhaber: Anette Stadtfeld

Standort: DocuSign

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Anette.Stadtfeld@kulzer-dental.com

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Matthias Hartmann

matthias.hartmann@kulzer-dental.com

PRRC

Sicherheitsstufe: E-Mail, Kontoauthentifizierung
(keine)Signaturübernahme: Hochgeladenes Signaturbild
Mit IP-Adresse: 89.246.249.146

Gesendet: 22.11.2022 11:42:41

Eingesehen: 22.11.2022 13:01:33

Signiert: 22.11.2022 13:02:00

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:

Akzeptiert: 22.11.2022 13:01:33

ID: 855b1909-22f2-4676-8f20-c5ea1f021efa

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Bearbeiterversandereignisse	Status	Zeitstempel
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Kopienereignisse	Status	Zeitstempel
Zeugen-Ereignisse	Signatur	Zeitstempel
Notarereignisse	Signatur	Zeitstempel
Umschlagereignisse – Überblick	Status	Zeitstempel
Umschlag gesendet	Hash-codiert/verschlüsselt	22.11.2022 11:42:41
Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	22.11.2022 13:01:33
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	22.11.2022 13:02:00
Abgeschlossen	Sicherheitsprüfung ausgeführt	22.11.2022 13:02:00
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Betreff: Mit DocuSign abschließen: Annex DoC Charisma Diamond MDR CZ korrigiert.docx

Quellumschlag:

Dokumentenseiten: 2

Signaturen: 1

Umschlagsteller:

Zertifikatsseiten: 4

Initialen: 0

Leonie Albrecht

Signatur mit Anleitung: Aktiviert

Leipziger Str. 2

Umschlag-ID-Stempel: Aktiviert

Hanau, Hessen 63450

Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien

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Status: Original

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Matthias Hartmann

Matthias.Hartmann@kulzer-dental.com

PRRC

Sicherheitsstufe: E-Mail, Kontoauthentifizierung
(keine)

Gesendet: 24.11.2022 14:21:08

Eingesehen: 24.11.2022 15:55:17

Signiert: 24.11.2022 15:55:33

Signaturübernahme: Hochgeladenes Signaturbild
Mit IP-Adresse: 77.179.101.81**Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:**

Akzeptiert: 24.11.2022 15:55:17

ID: 71999e0b-b917-42e7-ac8a-e2731a1d94eb

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Signiervorgang abgeschlossen

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