

**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 Classic**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*  
GMDN-Nummer / *GMDN code*  
UMDNS-Nummer / *UMDNS code*  
Basis-UDI-DI / *Basic UDI-DI*Q010101  
35870  
16-724  
++J0141103COMP010103c7Yder 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 4 der Technischen  
Dokumentation von Product Charisma Classic / *Further Applied  
standards see Technical Documentation of Product Charisma  
Classic, Version 4*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*

4

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 Classic**

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 /  
This article list is valid for the declaration of conformity version

**04**

| UDI-DI /<br>UDI-DI | Artikelnummer /<br>Article number | Name /<br>Name                           |
|--------------------|-----------------------------------|------------------------------------------|
| +J014660560760     | 66056076                          | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770     | 66056077                          | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780     | 66056078                          | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790     | 66056079                          | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800     | 66056080                          | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010     | 66056101                          | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020     | 66056102                          | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030     | 66056103                          | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040     | 66056104                          | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050     | 66056105                          | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060     | 66056106                          | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070     | 66056107                          | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100     | 66056110                          | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110     | 66056111                          | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120     | 66056112                          | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980     | 66096098                          | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010     | 66096101                          | PROC CHARISMA CLASSIC KIT 8X4G 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 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 Classic**

Наименование, тип или модел, партиден или  
сериен номер, евентуално произход и брой  
елементи / Name, type or model, batch or serial  
number, possibly sources and number of items

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

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

Q010101  
35870  
16-724  
++J0141103COMP010103c7Y

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 documents

EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Други приложени стандарти, вижте техническата  
документация на продукт Charisma Classic Версия 4  
Further Applied standards see Technical Documentation of  
Product Charisma Classic, Version 4

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

4

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 /  
*The medical device*

Charisma Classic

Номер на версия / *Version number*

04

Заменя Приложението от /  
*Replaces Annex from*

08.08.2024

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*

04

| UDI-DI / <i>UDI-DI</i> | Номер на артикул /<br><i>Article number</i> | Наименование / <i>Name</i>               |
|------------------------|---------------------------------------------|------------------------------------------|
| +J014660560760         | 66056076                                    | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770         | 66056077                                    | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780         | 66056078                                    | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790         | 66056079                                    | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800         | 66056080                                    | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010         | 66056101                                    | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020         | 66056102                                    | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030         | 66056103                                    | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040         | 66056104                                    | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050         | 66056105                                    | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060         | 66056106                                    | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070         | 66056107                                    | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100         | 66056110                                    | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110         | 66056111                                    | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120         | 66056112                                    | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980         | 66096098                                    | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010         | 66096101                                    | PROC CHARISMA CLASSIC KIT 8X4G 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 Classic**Název, typ nebo model, šarže nebo výrobní číslo,  
případně zdroje a počet kusů / *Name, type or  
model, batch or serial number, possibly sources and  
number of items*Seznam položek je uveden v příloze /  
*List of Articles see Annex*Kód EMDN / *EMDN-Code*  
Kód GMDN / *GMDN code*  
Kód UMDNS / *UMDNS code*  
Základní UDI-DI / *Basic UDI-DI*Q010101  
35870  
16-724  
++J0141103COMP010103c7Ytřídy / *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  
documents*EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Další použité normy najdete v technické dokumentaci k  
výrobku Charisma Classic verze 4  
*Further Applied standards see Technical Documentation of  
Product Charisma Classic, Version 4*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*

4

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 Classic**

Číslo verze / Version number

**04**

Nahrazuje přílohu ze dne /  
Replaces Annex from

**08.08.2024**

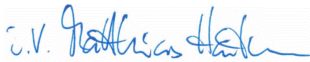
Tento seznam zboží platí pro verzi  
prohlášení o shodě / This article list is valid  
for the declaration of conformity version:

**04**

| UDI-DI / UDI-DI | Číslo zboží /<br>Article number | Název / Name                             |
|-----------------|---------------------------------|------------------------------------------|
| +J014660560760  | 66056076                        | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770  | 66056077                        | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780  | 66056078                        | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790  | 66056079                        | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800  | 66056080                        | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010  | 66056101                        | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020  | 66056102                        | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030  | 66056103                        | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040  | 66056104                        | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050  | 66056105                        | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060  | 66056106                        | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070  | 66056107                        | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100  | 66056110                        | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110  | 66056111                        | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120  | 66056112                        | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980  | 66096098                        | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010  | 66096101                        | PROC CHARISMA CLASSIC KIT 8X4G 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 Classic**

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  
++J0141103COMP010103c7Y

klassil / of class

IIa

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  
Muid rakenduvaid standardeid vt tehnilistest  
dokumentidest tootele Charisma Classic, Version 4  
Further Applied standards see Technical Documentation of  
Product Charisma Classic, Version 4

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

4

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 /  
The medical device

Versioni number / Version number

Asendab lisa alates /  
Replaces Annex from

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

**Charisma Classic**

**04**

**08.08.2024**

**04**

| UDI-DI / UDI-DI | Artikli number /<br>Article number | Nimi / Name                              |
|-----------------|------------------------------------|------------------------------------------|
| +J014660560760  | 66056076                           | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770  | 66056077                           | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780  | 66056078                           | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790  | 66056079                           | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800  | 66056080                           | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010  | 66056101                           | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020  | 66056102                           | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030  | 66056103                           | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040  | 66056104                           | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050  | 66056105                           | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060  | 66056106                           | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070  | 66056107                           | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100  | 66056110                           | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110  | 66056111                           | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120  | 66056112                           | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980  | 66096098                           | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010  | 66096101                           | PROC CHARISMA CLASSIC KIT 8X4G SYR       |

Hanau, 21.10.2024

Koht, kuupäev / Place, date

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

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 Classic**

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  
++J0141103COMP010103c7Y

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 Classic, versión 4  
*Further Applied standards see Technical Documentation of*  
*Product Charisma Classic, Version 4*

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*

4

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 /  
*The medical device*

Número de versión / *Version number*

Sustituye al Anexo del /  
*Replaces Annex from*

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

**Charisma Classic**

**04**

**08.08.2024**

**04**

| UDI-DI / <i>UDI-DI</i> | Número de artículo /<br><i>Article number</i> | Nombre / <i>Name</i>                     |
|------------------------|-----------------------------------------------|------------------------------------------|
| +J014660560760         | 66056076                                      | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770         | 66056077                                      | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780         | 66056078                                      | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790         | 66056079                                      | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800         | 66056080                                      | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010         | 66056101                                      | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020         | 66056102                                      | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030         | 66056103                                      | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040         | 66056104                                      | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050         | 66056105                                      | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060         | 66056106                                      | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070         | 66056107                                      | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100         | 66056110                                      | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110         | 66056111                                      | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120         | 66056112                                      | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980         | 66096098                                      | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010         | 66096101                                      | PROC CHARISMA CLASSIC KIT 8X4G SYR       |

Hanau, 21.10.2024

Lugar, fecha / *Place, date*

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

Nombre y cargo / *Name and function*

Dok.: 2057497

Version: 01

Página 1 de 1

ES/GB

**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 Classic**Επωνυμία, τύπος ή μοντέλο, παρτίδα ή αριθμός  
σειράς, πιθανές πηγές και αριθμός ειδών / Name,  
type or model, batch or serial number, possibly  
sources and number of items

Κατάλογος ειδών Παράρτημα / List of Articles see Annex

Κωδικός EMDN / EMDN-Code  
Κωδικός GMDN / GMDN code  
Κωδικός UMDNS / UMDNS code  
Βασικό UDI-DI / Basic UDI-DIQ010101  
35870  
16-724  
++J0141103COMP010103c7Y

κλάσης / 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 documentsEN ISO 4049 - Dentistry- Polymer-based restorative materials  
Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική  
τεκμηρίωση του  
προϊόντος Charisma Classic], έκδοση 4  
Further Applied standards see Technical Documentation of  
Product Charisma Classic, Version 4Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με  
/  
Conformity assessment procedure acc. toΚανονισμός 2017/745 για τα ιατροτεχνολογικά προϊόντα,  
Παράρτημα IX, Κεφάλαιο I, Τμήμα 2 και 3, και Κεφάλαιο III  
Medical Device Regulation 2017/745 Annex IX, Chapter I, Section  
2 and 3 and Chapter III

Κοινοποιημένος οργανισμός / Notified Body

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Γερμανία

CE 0197

Αριθμός καταχώρησης / Registration number:

HZ 1198082-1

Αριθμός έκδοσης / Version number

4

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*

Αριθμός έκδοσης / *Version number*

Αντικαθιστά το Παράρτημα από /  
*Replaces Annex from*

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

**Charisma Classic**

**04**

**08.08.2024**

**04**

| UDI-DI / <i>UDI-DI</i> | Αριθμός είδους /<br><i>Article number</i> | Όνομα / <i>Name</i>                      |
|------------------------|-------------------------------------------|------------------------------------------|
| +J014660560760         | 66056076                                  | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770         | 66056077                                  | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780         | 66056078                                  | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790         | 66056079                                  | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800         | 66056080                                  | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010         | 66056101                                  | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020         | 66056102                                  | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030         | 66056103                                  | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040         | 66056104                                  | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050         | 66056105                                  | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060         | 66056106                                  | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070         | 66056107                                  | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100         | 66056110                                  | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110         | 66056111                                  | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120         | 66056112                                  | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980         | 66096098                                  | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010         | 66096101                                  | PROC CHARISMA CLASSIC KIT 8X4G SYR       |

Hanau, 21.10.2024

Τόπος, ημερομηνία / *Place, date*



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

Ονοματεπώνυμο και τίτλος / *Name and function*

Αρ. εγγράφου:2057497

Έκδοση: 01

Σελίδα 1 από 1

GR/GB

**IZJAVA O USKLAĐENOSTI / DECLARATION OF CONFORMITY**

Naziv i adresa tvrtke /  
*Name and address of the company*

**Kulzer GmbH**  
Leipziger Straße 2, 63450 Hanau  
Njemačka / Germany

SRN: DE-MF-000007705

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

medicinski proizvod / *the medical device*

**Charisma Classic**

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*

++J0141103COMP010103c7Y

klase / *of class*

Ila

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 Classic, verzija 4  
*Further Applied standards see Technical Documentation of Product Charisma Classic, Version 4*

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*

4

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 /  
The medical device

Charisma Classic

Broj verzije / Version number

04

Zamjenjuje Dodatak od /  
Replaces Annex from

08.08.2024

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

04

| UDI-DI / UDI-DI | Broj artikla /<br>Article number | Naziv / Name                             |
|-----------------|----------------------------------|------------------------------------------|
| +J014660560760  | 66056076                         | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770  | 66056077                         | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780  | 66056078                         | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790  | 66056079                         | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800  | 66056080                         | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010  | 66056101                         | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020  | 66056102                         | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030  | 66056103                         | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040  | 66056104                         | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050  | 66056105                         | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060  | 66056106                         | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070  | 66056107                         | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100  | 66056110                         | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110  | 66056111                         | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120  | 66056112                         | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980  | 66096098                         | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010  | 66096101                         | PROC CHARISMA CLASSIC KIT 8X4G 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-000007705

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

az orvostechikai eszköz / the medical device

**Charisma Classic**

Név, típus vagy modell, tétel vagy sorozatszám,  
esetleg források és tételek száma / Name, type or  
model, batch or serial number, possibly sources and  
number of items

A cikkek listáját lásd a mellékletben / List of Articles see Annex

EMDN kód / EMDN-Code  
GMDN kód / GMDN code  
UMDNS kód / UMDNS code  
Alapvető UDI-DI / Basic UDI-DI

Q010101  
35870  
16-724  
++J0141103COMP010103c7Y

osztálya / of class

Ila

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 documents

EN ISO 4049 - Dentistry– Polymer-based restorative materials  
További alkalmazott szabványokat lásd a műszaki dokumentációban,  
termék: Charisma Classic, 4. verzió  
Further Applied standards see Technical Documentation of  
Product Charisma Classic, Version 4

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

Az orvostechikai eszközökről szóló, 2017/745 rendelet IX. függeléke,  
az I. fejezet 2. és 3. szakasza, és a III. fejezet  
Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2  
and 3 and Chapter III

Bejelentett szervezet / Notified Body

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Németország

CE 0197

Regisztrációs szám / Registration number:

HZ 1198082-1

Verziószám / Version number

4

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 Classic

Verziószám / *Version number*

04

Felváltja a mellékletet ettől /  
*Replaces Annex from*

08.08.2024

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

04

| UDI-DI / <i>UDI-DI</i> | Cikkszám /<br><i>Article number</i> | Név / <i>Name</i>                        |
|------------------------|-------------------------------------|------------------------------------------|
| +J014660560760         | 66056076                            | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770         | 66056077                            | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780         | 66056078                            | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790         | 66056079                            | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800         | 66056080                            | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010         | 66056101                            | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020         | 66056102                            | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030         | 66056103                            | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040         | 66056104                            | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050         | 66056105                            | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060         | 66056106                            | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070         | 66056107                            | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100         | 66056110                            | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110         | 66056111                            | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120         | 66056112                            | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980         | 66096098                            | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010         | 66096101                            | PROC CHARISMA CLASSIC KIT 8X4G 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-000007705

**Prisiimdami visą atsakomybę pareiškiame, kad / We declare under our sole responsibility that**medicinos prietaisas / *the medical device***Charisma Classic**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*

Q010101

GMDN kodas / *GMDN code*

35870

UMDNS kodas / *UMDNS code*

16-724

Pagrindinis UDI-DI / *Basic UDI-DI*

++J0141103COMP010103c7Y

klasės / *of class*

IIa

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 Classic, techninėje dokumentacijoje, 3  
versijoje*Further Applied standards see Technical Documentation of  
Product Charisma Classic, Version 3*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*

4

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 /  
The medical device

Charisma Classic

Versijos numeris / Version number

04

Pakeičia Priedą nuo /  
Replaces Annex from

08.08.2024

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

04

| UDI-DI / UDI-DI | Prekės numeris /<br>Article number | Pavadinimas / Name                       |
|-----------------|------------------------------------|------------------------------------------|
| +J014660560760  | 66056076                           | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770  | 66056077                           | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780  | 66056078                           | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790  | 66056079                           | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800  | 66056080                           | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010  | 66056101                           | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020  | 66056102                           | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030  | 66056103                           | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040  | 66056104                           | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050  | 66056105                           | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060  | 66056106                           | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070  | 66056107                           | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100  | 66056110                           | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110  | 66056111                           | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120  | 66056112                           | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980  | 66096098                           | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010  | 66096101                           | PROC CHARISMA CLASSIC KIT 8X4G SYR       |

21.10.2024  
Hanau,

  
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-000007705

**Mēs vienīgi uz savu atbildību deklarējam, ka / We declare under our sole responsibility that**medicīniskā ierīce / *the medical device***Charisma Classic**Preču nosaukums, tips vai modelis, partijas vai  
sērijas numurs, iespējamie avoti un skaits / *Name,  
type or model, batch or serial number, possibly  
sources and number of items*Preču sarakstu skatiet pielikumā / *List of Articles see Annex*EMDN kods / *EMDN-Code*  
GMDN kods / *GMDN code*  
UMDNS kods / *UMDNS code*  
Pamata UDI-DI / *Basic UDI-DI*Q010101  
35870  
16-724  
++J0141103COMP010103c7Yklase / *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  
documents*EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Citus izmantotos standartus skatiet tehniskajā dokumentācijā par  
produktu Charisma Classic, 4 versija  
*Further Applied standards see Technical Documentation of  
Product Charisma Classic, Version 4*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*

4

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 /  
The medical device

Charisma Classic

Versijas numurs / Version number

04

Aizstāj pielikumu, kas datēts ar /  
Replaces Annex from

08.08.2024

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

04

| UDI-DI / UDI-DI | Preces numurs /<br>Article number | Nosaukums / Name                         |
|-----------------|-----------------------------------|------------------------------------------|
| +J014660560760  | 66056076                          | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770  | 66056077                          | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780  | 66056078                          | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790  | 66056079                          | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800  | 66056080                          | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010  | 66056101                          | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020  | 66056102                          | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030  | 66056103                          | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040  | 66056104                          | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050  | 66056105                          | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060  | 66056106                          | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070  | 66056107                          | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100  | 66056110                          | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110  | 66056111                          | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120  | 66056112                          | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980  | 66096098                          | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010  | 66096101                          | PROC CHARISMA CLASSIC KIT 8X4G 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 Classic**

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  
++J0141103COMP010103c7Y

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 Classic, wersja 4  
Further Applied standards see Technical Documentation of  
Product Charisma Classic, Version 4

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

4

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 /  
The medical device

Charisma Classic

Numer wersji / Version number

04

Zastępuje załącznik z dnia /  
Replaces Annex from

08.08.2024

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

04

| UDI-DI / UDI-DI | Numer wyrobu /<br>Article number | Nazwa / Name                             |
|-----------------|----------------------------------|------------------------------------------|
| +J014660560760  | 66056076                         | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770  | 66056077                         | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780  | 66056078                         | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790  | 66056079                         | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800  | 66056080                         | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010  | 66056101                         | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020  | 66056102                         | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030  | 66056103                         | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040  | 66056104                         | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050  | 66056105                         | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060  | 66056106                         | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070  | 66056107                         | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100  | 66056110                         | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110  | 66056111                         | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120  | 66056112                         | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980  | 66096098                         | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010  | 66096101                         | PROC CHARISMA CLASSIC KIT 8X4G SYR       |

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

**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 Classic**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*

Q010101

Cod GMDN / *GMDN code*

35870

Cod UMDNS / *UMDNS code*

16-724

UDI-DI de bază / *Basic UDI-DI*

++J0141103COMP010103c7Y

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 Classic, Versiunea 4  
*Further Applied standards see Technical Documentation of  
Product Charisma Classic, Version 4*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*

4

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 /  
*The medical device*

Charisma Classic

Număr versiune / *Version number*

04

Înlocuiește Anexa de la /  
*Replaces Annex from*

08.08.2024

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

04

| UDI-DI / <i>UDI-DI</i> | Număr articol /<br><i>Article number</i> | Nume / <i>Name</i>                       |
|------------------------|------------------------------------------|------------------------------------------|
| +J014660560760         | 66056076                                 | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770         | 66056077                                 | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780         | 66056078                                 | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790         | 66056079                                 | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800         | 66056080                                 | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010         | 66056101                                 | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020         | 66056102                                 | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030         | 66056103                                 | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040         | 66056104                                 | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050         | 66056105                                 | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060         | 66056106                                 | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070         | 66056107                                 | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100         | 66056110                                 | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110         | 66056111                                 | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120         | 66056112                                 | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980         | 66096098                                 | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010         | 66096101                                 | PROC CHARISMA CLASSIC KIT 8X4G 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 Classic**

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  
++J0141103COMP010103c7Y

razreda / *of class*

Ila

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 Classic, različica 4  
*Further Applied standards see Technical Documentation of Product Charisma Classic, Version 4*

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*

4

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 /  
The medical device

Charisma Classic

Številka različice / Version number

04

Nadomešča Prilogo z dne /  
Replaces Annex from

08.08.2024

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

04

| UDI-DI / UDI-DI | Številka artikla /<br>Article number | Ime / Name                               |
|-----------------|--------------------------------------|------------------------------------------|
| +J014660560760  | 66056076                             | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770  | 66056077                             | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780  | 66056078                             | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790  | 66056079                             | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800  | 66056080                             | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010  | 66056101                             | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020  | 66056102                             | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030  | 66056103                             | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040  | 66056104                             | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050  | 66056105                             | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060  | 66056106                             | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070  | 66056107                             | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100  | 66056110                             | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110  | 66056111                             | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120  | 66056112                             | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980  | 66096098                             | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010  | 66096101                             | PROC CHARISMA CLASSIC KIT 8X4G SYR       |

Hanau, 21.10.2024

Kraj, datum / Place, date

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

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 Classic**

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

++J0141103COMP010103c7Y

triedy / of class

IIa

podľa pravidiel / 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.**

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 4 k  
produktu Charisma Classic  
Further Applied standards see Technical Documentation of  
Product Charisma Classic, Version 4.

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

4

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 /  
The medical device

Charisma Classic

Číslo verzie / Version number

04

Nahrádza prílohu z /  
Replaces Annex from

08.08.2024

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

04

| UDI-DI / UDI-DI | Číslo položky /<br>Article number | Meno / Name                              |
|-----------------|-----------------------------------|------------------------------------------|
| +J014660560760  | 66056076                          | CHARISMA CLASSIC SYR REFILL 1X4G - A1    |
| +J014660560770  | 66056077                          | CHARISMA CLASSIC SYR REFILL 1X4G - A2    |
| +J014660560780  | 66056078                          | CHARISMA CLASSIC SYR REFILL 1X4G - A3    |
| +J014660560790  | 66056079                          | CHARISMA CLASSIC SYR REFILL 1X4G - A3.5  |
| +J014660560800  | 66056080                          | CHARISMA CLASSIC SYR REFILL 1X4G - A4    |
| +J014660561010  | 66056101                          | CHARISMA CLASSIC SYR REFILL 1X4G - B1    |
| +J014660561020  | 66056102                          | CHARISMA CLASSIC SYR REFILL 1X4G - B2    |
| +J014660561030  | 66056103                          | CHARISMA CLASSIC SYR REFILL 1X4G - B3    |
| +J014660561040  | 66056104                          | CHARISMA CLASSIC SYR REFILL 1X4G - C2    |
| +J014660561050  | 66056105                          | CHARISMA CLASSIC SYR REFILL 1X4G - OA2   |
| +J014660561060  | 66056106                          | CHARISMA CLASSIC SYR REFILL 1X4G - OA3   |
| +J014660561070  | 66056107                          | CHARISMA CLASSIC SYR REFILL 1X4G - OA3.5 |
| +J014660561100  | 66056110                          | CHARISMA CLASSIC SYR ASSORTMENT 4X4G     |
| +J014660561110  | 66056111                          | CHARISMA CLASSIC SYR ASSORTMENT 8X4G     |
| +J014660561120  | 66056112                          | CHARISMA CLASSIC SYR SAMPLE KIT 1X1G -A2 |
| +J014660960980  | 66096098                          | PROC CHARISMA CLASSIC KIT 6X4G SYR       |
| +J014660961010  | 66096101                          | PROC CHARISMA CLASSIC KIT 8X4G 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

|                                                                                                     |                |                                    |
|-----------------------------------------------------------------------------------------------------|----------------|------------------------------------|
| Umschlag-ID: 55DD683CB3C5422BAADB2586300C04CA                                                       |                | Status: Abgeschlossen              |
| Betreff: Mit Docusign abschließen: Charisma Classic_MDR_DoC_V04_2024-10-xx_Annex_V04_2024-10-xx.pdf |                |                                    |
| Quellumschlag:                                                                                      |                |                                    |
| Dokumentenseiten: 28                                                                                | Signaturen: 28 | Umschlagsteller:                   |
| Zertifikatsseiten: 1                                                                                | Initialen: 0   | Daniela Wienhold                   |
| Signatur mit Anleitung: Aktiviert                                                                   |                | Leipziger Str. 2                   |
| Umschlag-ID-Stempel: Aktiviert                                                                      |                | Hanau, Hessen 63450                |
| Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien                                 |                | Daniela.Wienhold@kulzer-dental.com |
|                                                                                                     |                | IP-Adresse: 52.233.243.152         |

Eintragsverfolgung

|                     |                                    |                    |
|---------------------|------------------------------------|--------------------|
| Status: Original    | Inhaber: Daniela Wienhold          | Standort: DocuSign |
| 18.10.2024 11:59:57 | Daniela.Wienhold@kulzer-dental.com |                    |

| Unterzeichnerereignisse | Signatur | Zeitstempel |
|-------------------------|----------|-------------|
|-------------------------|----------|-------------|

|                                                          |                                                                                   |                                 |
|----------------------------------------------------------|-----------------------------------------------------------------------------------|---------------------------------|
| Matthias Hartmann                                        |  | Gesendet: 18.10.2024 12:06:43   |
| matthias.hartmann@kulzer-dental.com                      |                                                                                   | Eingesehen: 21.10.2024 09:01:56 |
| Head of Global Quality, Regulatory & Scientific Services |                                                                                   | Signiert: 21.10.2024 09:02:22   |
| Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine) | Signaturübernahme: Hochgeladenes Signaturbild<br>Mit IP-Adresse: 77.186.183.50    |                                 |

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:  
Nicht über DocuSign angeboten

| Vor-Ort-Unterzeichner – Ereignisse | Signatur | Zeitstempel |
|------------------------------------|----------|-------------|
|------------------------------------|----------|-------------|

| Bearbeiterversandereignisse | Status | Zeitstempel |
|-----------------------------|--------|-------------|
|-----------------------------|--------|-------------|

| Beauftragtenzustellereignisse | Status | Zeitstempel |
|-------------------------------|--------|-------------|
|-------------------------------|--------|-------------|

| Vermittlerversandereignisse | Status | Zeitstempel |
|-----------------------------|--------|-------------|
|-----------------------------|--------|-------------|

| Zertifizierter Versand - Ereignisse | Status | Zeitstempel |
|-------------------------------------|--------|-------------|
|-------------------------------------|--------|-------------|

| Kopienereignisse | Status | Zeitstempel |
|------------------|--------|-------------|
|------------------|--------|-------------|

|                                                          |         |                                 |
|----------------------------------------------------------|---------|---------------------------------|
| Anette Stadtfeld                                         | Kopiert | Gesendet: 18.10.2024 12:06:43   |
| Anette.Stadtfeld@kulzer-dental.com                       |         | Eingesehen: 22.10.2024 09:46:50 |
| Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine) |         |                                 |

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:  
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| Zeugen-Ereignisse | Signatur | Zeitstempel |
|-------------------|----------|-------------|
|-------------------|----------|-------------|

| Notarereignisse | Signatur | Zeitstempel |
|-----------------|----------|-------------|
|-----------------|----------|-------------|

| Umschlagereignisse – Überblick | Status | Zeitstempel |
|--------------------------------|--------|-------------|
|--------------------------------|--------|-------------|

|                              |                               |                     |
|------------------------------|-------------------------------|---------------------|
| Umschlag gesendet            | Hash-codiert/verschlüsselt    | 18.10.2024 12:06:43 |
| Zertifiziert zugestellt      | Sicherheitsprüfung ausgeführt | 21.10.2024 09:01:56 |
| Signiervorgang abgeschlossen | Sicherheitsprüfung ausgeführt | 21.10.2024 09:02:22 |
| Abgeschlossen                | Sicherheitsprüfung ausgeführt | 21.10.2024 09:02:22 |

| Zahlungen | Status | Zeitstempel |
|-----------|--------|-------------|
|-----------|--------|-------------|