

**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 Flow**Bezeichnung, Typ oder Modell, Chargen- oder  
Seriennummer, ev. Herkunft und Stückzahl / *Name,  
type or model, batch or serial number, possibly  
sources and number of items*Artikelliste siehe Anhang / *List of Articles see Annex*EMDN-Nummer / *EMDN-Code*  
GMDN-Nummer / *GMDN code*  
UMDNS-Nummer / *UMDNS code*  
Basis-UDI-DI / *Basic UDI-DI*Q 010101  
35870  
16-724  
++J0141103COMP010103h8Ader 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 02 der Technischen  
Dokumentation von Produkt Charisma Flow/ *Further Applied  
standards see Technical Documentation of Product Charisma  
Flow, Version 02*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*

02

Ersetzt Konformitätserklärung vom /  
*Replaces Declaration of Conformity from*

29.11.2022

Hanau, 23.10.2024

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 Flow**

Versionsnummer Artikelliste/  
Version number article list

02

Ersetzt Artikelliste vom /  
Replaces article list from

29.11.2022

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

| UDI-DI /<br>UDI-DI | Artikelnummer /<br>Article number | Name /<br>Name                         |
|--------------------|-----------------------------------|----------------------------------------|
| +J014660154950     | 66015495                          | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960     | 66015496                          | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970     | 66015497                          | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980     | 66015498                          | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990     | 66015499                          | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000     | 66015500                          | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040     | 66015504                          | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010     | 66015501                          | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020     | 66015502                          | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450     | 66095845                          | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460     | 66095846                          | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470     | 66095847                          | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480     | 66095848                          | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490     | 66095849                          | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500     | 66095850                          | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510     | 66095851                          | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520     | 66095852                          | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530     | 66095853                          | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

Ort, Datum / Place, date

i.V. 

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

Name und Funktion / Name and function

## ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ / *DECLARATION OF CONFORMITY*

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

Kulzer GmbH  
 Leipziger Straße 2, 63450 Hanau  
 Германия / Germany

SRN: DE-MF-000007705

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

медицинското изделие / *the medical device*

**Charisma Flow**

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  
 ++J01411103COMP010103h8A

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 Flow Версия 02  
*Further Applied standards see Technical Documentation of  
 Product Charisma Flow, Version 02*

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*

02

Заменя Декларация за съответствие от /  
*Replaces Declaration of Conformity from*

29.11.2022

Ханау, 23.10.2024

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 Flow

Номер на версия / *Version number*

02

Заменя Приложението от /  
*Replaces Annex from*

29.11.2022

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*

02

| UDI-DI / <i>UDI-DI</i> | Номер на артикул /<br><i>Article number</i> | Наименование / <i>Name</i>             |
|------------------------|---------------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                                    | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                                    | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                                    | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                                    | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                                    | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                                    | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                                    | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                                    | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                                    | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

23.10.2024

Ханау,

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*


**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 Smart**

 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  
 ++J0141103COMP010103h8A

 třídy / *of class*

IIa

 podle pravidla / *according to rule*

 8-1, 19-3 podle přílohy VIII k nařízení 2017/745 o zdravotnických  
 prostředcích / *according to Annex VIII of Medical Device Regulation  
 2017/745*

**splňuje všechna ustanovení nařízení 2017/745 o zdravotnických prostředcích, která se ho týkají. /  
*meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***

 Použité harmonizované normy, národní normy nebo  
 jiné normativní dokumenty / *Applied harmonised  
 standards, national standards or other normative  
 documents*

 EN ISO 4049 - Dentistry- Polymer-based restorative materials  
 Další použité normy najdete v technické dokumentaci k  
 výrobku Charisma Flow, verze 02  
*Further Applied standards see Technical Documentation of  
 Product Charisma Flow, Version 02*

 Procedura posouzení shody podle /  
*Conformity assessment procedure acc. to*

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

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

 Notifikovaná osoba / *Notified Body*

 TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Německo

CE 0197

 Registrační číslo / *Registration number*:

HZ 1198082-1

 Číslo verze / *Version number*

02

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

29.11.2022

Hanau, 23.10.2024

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 Flow**

Číslo verze / *Version number*

02

Nahrazuje přílohu ze dne /  
*Replaces Annex from*

29.11.2022

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

02

| UDI-DI / <i>UDI-DI</i> | Číslo zboží /<br><i>Article number</i> | Název / <i>Name</i>                    |
|------------------------|----------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                               | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                               | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                               | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                               | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                               | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                               | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                               | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                               | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                               | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                               | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                               | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                               | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                               | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                               | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

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

Místo, datum / *Place, date*

Jméno a funkce / *Name and function*

**OVERENSSTEMMELSESERKLÆRING / DECLARATION OF CONFORMITY**Virksomhedens navn og adresse /  
*Name and address of the company***Kulzer GmbH**  
Leipziger Straße 2, D-63450 Hanau  
Tyskland / Germany  
SRN: DE-MF-000007705**Vi erklærer hermed på eget ansvar, at / We declare under our sole responsibility that**det medicinske udstyr / *the medical device***Charisma Flow**Betegnelse, type eller model, batch- eller  
serienummer samt eventuelt oprindelse og antal  
emner / *Name, type or model, batch or serial  
number, possibly sources and number of items*Produktlisten kan ses i bilaget / *List of Articles see Annex*EMDN-kode / *EMDN-Code*  
GMDN-kode / *GMDN code*  
UMDNS-kode / *UMDNS code*  
Grundlæggende UDI-DI / *Basic UDI-DI*Q 010101  
35870  
16-724  
++J0141103COMP010103h8Ai klasse / *of class*

IIa

i henhold til artikel / *according to rule*8-1, 19-3 i bilag VIII i Europa-Parlamentets og Rådets forordning  
(EU) 2017/745 om medicinsk udstyr / *according to Annex VIII of  
Medical Device Regulation 2017/745***lever op til alle de relevante bestemmelser i forordning (EU) 2017/745 om medicinsk udstyr. /  
*meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***Anvendte harmoniserede standarder, nationale  
standarder eller andre normative dokumenter /  
*Applied harmonised standards, national standards  
or other normative documents*EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Andre anvendte standarder kan ses i det tekniske  
dokumentationsmateriale til produktet Charisma Flow, version 02  
*Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 02*Overensstemmelsesvurderingsprocedure iht. /  
*Conformity assessment procedure acc. to*Forordning (EU) 2017/745 om medicinsk udstyr, bilag IX, kapitel I,  
afsnit 2 og 3 samt kapitel III  
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section  
2 and 3 and Chapter III*Underrettet organ / *Notified Body*TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
D-90431 Nürnberg, Tyskland

CE 0197

Registreringsnummer / *Registration number:*

HZ 1198082-1

Versionsnummer / *Version number*

02

Erstatter overensstemmelseserklæring fra /  
*Replaces Declaration of Conformity from*

29.11.2022

Hanau, 23.10.2024

på vegne af Dr. Matthias Hartmann  
Head of Global Quality, Regulatory & Scientific Services  
**Kulzer GmbH**Sted, dato / *Place, date*Navn og stilling / *Name and function*Denne konformitetserklæring gælder i 2 år i forbindelse med frigivelsesdokumenterne for det aktuelle parti af produceret  
medicinsk udstyr / *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**  
**Bilag / Annex: Overensstemmelseserklæring / Declaration of Conformity**

Det medicinske udstyr /  
*The medical device*

**Charisma Flow**

Versionsnummer / *Version number*

02

Erstatter bilag fra /  
*Replaces Annex from*

29.11.2022

Denne artikelliste er gyldig i forbindelse med  
 overensstemmelseserklæringen version /  
*This article list is valid for the declaration of  
 conformity version*

02

| <b>UDI-DI / UDI-DI</b> | <b>Varenummer /<br/>Article number</b> | <b>Betegnelse / Name</b>               |
|------------------------|----------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                               | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                               | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                               | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                               | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                               | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                               | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                               | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                               | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                               | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                               | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                               | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                               | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                               | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                               | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

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

Sted, dato / *Place, date*

Navn og stilling / *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 Smart**

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  
++J0141103COMP010103h8A

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 Flow, Version 2.  
Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 2.

Vastavushindamismenetlus vastavalt /  
Conformity assessment procedure acc. to

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

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

Teavitatud asutus / Notified Body

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Saksamaa

CE 0197

Registreerimisnumber / Registration number:

HZ 1198082-1

Versiooni number / Version number

02

Asendab vastavusdeklaratsiooni alates /  
Replaces Declaration of Conformity from

29.11.2022

Hanau, 23.10.2024

  
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**

Meditisiiniseade /  
The medical device

Charisma Flow

Versioni number / Version number

02

Asendab lisa alates /  
Replaces Annex from

29.11.2022

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

02

| UDI-DI / UDI-DI | Artikli number /<br>Article number | Nimi / Name                            |
|-----------------|------------------------------------|----------------------------------------|
| +J014660154950  | 66015495                           | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960  | 66015496                           | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970  | 66015497                           | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980  | 66015498                           | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990  | 66015499                           | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000  | 66015500                           | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040  | 66015504                           | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010  | 66015501                           | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020  | 66015502                           | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450  | 66095845                           | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460  | 66095846                           | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470  | 66095847                           | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480  | 66095848                           | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490  | 66095849                           | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500  | 66095850                           | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510  | 66095851                           | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520  | 66095852                           | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530  | 66095853                           | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

23.10.2024  
Hanau,

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 Smart**

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*

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16-724  
++J0141103COMP010103h8A

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 Flow, versión 02  
*Further Applied standards see Technical Documentation of*  
*Product Charisma Flow, Version 02*

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*

02

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

29.11.2022

Hanau, 23.10.2024

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

Lugar, fecha / *Place, date*

Nombre y cargo / *Name and function*

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



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

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

Número de versión / *Version number* 02

Sustituye al Anexo del / 29.11.2022  
*Replaces Annex from*

Esta lista de artículos es válida para la 02  
 versión de la declaración de conformidad /  
*This article list is valid for the declaration of*  
*conformity version*

| UDI-DI / <i>UDI-DI</i> | Número de artículo /<br><i>Article number</i> | Nombre / <i>Name</i>                   |
|------------------------|-----------------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                                      | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                                      | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                                      | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                                      | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                                      | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                                      | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                                      | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                                      | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                                      | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                                      | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                                      | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                                      | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                                      | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                                      | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                                      | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                                      | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                                      | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                                      | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

Lugar, fecha / *Place, date*

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

Nombre y cargo / *Name and function*

**VAATIMUSTENMUKAISUUSVAKUUTUS / DECLARATION OF CONFORMITY**

Yhtiön nimi ja osoite /  
Name and address of the company

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

**Vakuutamme yksinomaisella vastuullamme, että / We declare under our sole responsibility that**

lääkinnällinen laite / the medical device

**Charisma Flow**

Laitteen nimi, tyyppi tai malli, erä- tai sarjanumero,  
mahdolliset lähteet ja lukumäärä / Name, type or  
model, batch or serial number, possibly sources and  
number of items

Artikkeliluettelo, ks. liite / List of Articles see Annex

EMDN-koodi / EMDN-Code  
GMDN-koodi / GMDN code  
UMDNS-koodi / UMDNS code  
Perus-UDI-DI / Basic UDI-DI

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35870  
16-724  
++J0141103COMP010103h8A

luokka / of class

Ila

säädös / according to rule

8-1, 19-3 lääkitämisistä laitteista annetun asetuksen 2017/745  
liitteen VIII mukaan / according to Annex VIII of Medical Device  
Regulation 2017/745

**täyttää kaikki lääkitämisistä laitteista annetun asetuksen 2017/745 soveltuvat vaatimukset. /  
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.**

Soveltuvat harmonisoidut standardit, kansalliset  
standardit tai muut säädökset / Applied harmonised  
standards, national standards or other normative  
documents

EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Muut sovellettavat standardit, ks. tekniset tiedot  
tuotteesta Charisma Flow, versio 02  
Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 02

Vaatimustenmukaisuuden arviointimenettelyn perusta  
/  
Conformity assessment procedure acc. to

Asetus lääkitämisistä laitteista 2017/745, liite IX, I luku, 2 ja  
3 kohta ja III luku

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

Ilmoitettu laitos / Notified Body

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Saksa

CE 0197

Rekisteröintinumero / Registration number:

HZ 1198082-1

Versionumero / Version number

02

Korvaa vaatimustenmukaisuusvakuutuksen /  
Replaces Declaration of Conformity from

29.11.2022

Hanau, 23.10.2024

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

Paikka, päiväys / Place, date

Nimi ja asema / Name and function

Tämä vaatimustenmukaisuusvakuutus on voimassa 2 vuotta tuotettujen laitteiden vastaavan erän julkaisuasiakirjojen kanssa.  
This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced  
devices.

**Artikkeliluettelo / List of Articles****Liite / Annex: Vaatimustenmukaisuusvakuutus / Declaration of Conformity**Lääkinnällinen laite /  
The medical device**Charisma Flow**

Versionumero / Version number

02

Korvaa liitteen /  
Replaces Annex from

29.11.2022

Tämä artikkeliluettelo pätee  
vaatimustenmukaisuusvakuutuksen versioon /  
This article list is valid for the declaration of  
conformity version

02

| UDI-DI / UDI-DI | Artikkelinumero /<br>Article number | Nimi / Name                            |
|-----------------|-------------------------------------|----------------------------------------|
| +J014660154950  | 66015495                            | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960  | 66015496                            | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970  | 66015497                            | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980  | 66015498                            | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990  | 66015499                            | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000  | 66015500                            | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040  | 66015504                            | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010  | 66015501                            | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020  | 66015502                            | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450  | 66095845                            | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460  | 66095846                            | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470  | 66095847                            | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480  | 66095848                            | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490  | 66095849                            | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500  | 66095850                            | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510  | 66095851                            | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520  | 66095852                            | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530  | 66095853                            | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

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

Paikka, päiväys / Place, date

Nimi ja asema / Name and function

**DÉCLARATION DE CONFORMITÉ / DECLARATION OF CONFORMITY**

Nom et adresse de la société /  
*Name and address of the company*

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

**Nous déclarons sous notre seule responsabilité que / We declare under our sole responsibility that**  
le dispositif médical / *the medical device*

**Charisma Flow**

Nom, type ou modèle, numéro de lot ou de série,  
éventuellement sources et nombre d'articles /  
*Name, type or model, batch or serial number,*  
*possibly sources and number of items*

Liste des articles voir l'Annexe / *List of Articles see Annex*

Code EMDN / *EMDN-Code*  
Code GMDN / *GMDN code*  
code UMDNS / *UMDNS code*  
UDI-DI de base / *Basic UDI-DI*

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35870  
16-724  
++J0141103COMP010103h8A

de classe / *of class*

Ila

selon la règle / *according to rule*

8-1, 19-3 conformément à l'Annexe VIII du Règlement des Dispositifs Médicaux 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

**répond à toutes les dispositions du Règlement des Dispositifs Médicaux 2017/745 qui lui sont applicables. / meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.**

Application de normes harmonisées, de normes nationales ou d'autres documents normatifs /  
*Applied harmonised standards, national standards or other normative documents*

EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Autres normes appliquées voir Documentation technique du produit Charisma Flow, version 02  
*Further Applied standards see Technical Documentation of Product Charisma Flow, Version 02*

Procédure d'évaluation de la conformité selon /  
*Conformity assessment procedure acc. to*

Règlement relatif aux dispositifs médicaux 2017/745 Annexe IX, Chapitre I, Paragraphes 2 et 3 et Chapitre III

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

Organisme notifié / *Notified Body*

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Allemagne

CE 0197

Numéro d'enregistrement / *Registration number*

HZ 1198082-1

Numéro de version / *Version number*

02

Remplace la Déclaration de conformité de /  
*Replaces Declaration of Conformity from*

29.11.2022

Hanau, 23.10.2024

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

Lieu, date / *Place, date*

Nom et fonction / *Name and function*

Cette déclaration de conformité est valable 2 ans en relation avec les documents de libération pour le lot respectif des dispositifs médicaux fabriqués / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*



## Déclaration de conformité / *Declaration of Conformity* Annexe / *Annex* : Liste des articles / *List of Articles*

Le dispositif médical /  
*The medical device*

**Charisma Flow**

Numéro de version / *Version number*

02

Remplace l'annexe de /  
*Replaces Annex from*

29.11.2022

Cette liste d'articles est valable pour la  
 déclaration de conformité, version / *This*  
*article list is valid for the declaration of*  
*conformity version*

02

| UDI-DI / <i>UDI-DI</i> | Numéro de référence /<br><i>Article number</i> | Nom / <i>Name</i>                      |
|------------------------|------------------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                                       | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                                       | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                                       | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                                       | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                                       | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                                       | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                                       | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                                       | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                                       | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                                       | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                                       | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                                       | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                                       | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                                       | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                                       | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                                       | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                                       | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                                       | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

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

Lieu, date / *Place, date*

Nom et fonction / *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 Smart**

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*

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16-724  
++J0141103COMP010103h8A

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 documents*

EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική  
τεκμηρίωση του  
προϊόντος Charisma Flow, έκδοση 02  
*Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 02*

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*

02

Αντικαθιστά τη δήλωση συμμόρφωσης από /  
*Replaces Declaration of Conformity from*

29.11.2022

Hanau, 23.10.2024

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

Τόπος, ημερομηνία / *Place,  
date*

Ονοματεπώνυμο και τίτλος / *Name and function*

Αυτή η δήλωση συμμόρφωσης ισχύει για 2 χρόνια σε σχέση με τα έγγραφα κυκλοφορίας για την αντίστοιχη παρτίδα των παραγόμενων προϊόντων. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*



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

Το ιατροτεχνολογικό προϊόν / *The medical device* **Charisma Flow**

Αριθμός έκδοσης / *Version number* 02

Αντικαθιστά το Παράρτημα από / *Replaces Annex from* 29.11.2022

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

| UDI-DI / <i>UDI-DI</i> | Αριθμός είδους / <i>Article number</i> | Όνομα / <i>Name</i>                    |
|------------------------|----------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                               | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                               | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                               | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                               | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                               | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                               | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                               | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                               | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                               | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                               | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                               | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                               | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                               | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                               | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

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

Τόπος, ημερομηνία / *Place, date*

Ονοματεπώνυμο και τίτλος / *Name and function*

**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 Smart**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*

++J0141103COMP010103h8A

klase / *of class*

IIa

u skladu s pravilom / *according to rule*8-1, 19-3 u skladu s Dodatkom VIII Uredbe 2017/745 o medicinskim proizvodima / *according to Annex VIII of Medical Device Regulation 2017/745***ispunjava sve odredbe Uredbe 2017/745 o medicinskim proizvodima koje se na njega odnose. / meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.**Primijenjene usklađene norme, državne norme ili drugi normativni dokumenti / *Applied harmonised standards, national standards or other normative documents*EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod Charisma Flow, verzija 02  
*Further Applied standards see Technical Documentation of Product Charisma Flow, Version 02*Postupak procjene usklađenosti prema /  
*Conformity assessment procedure acc. to*

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

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

CE 0197

Registracijski broj / *Registration number*

HZ 1198082-1

Broj verzije / *Version number*

02

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

29.11.2022

Hanau, 23.10.2024

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 Flow

Broj verzije / Version number

02

Zamjenjuje Dodatak od /  
Replaces Annex from

29.11.2022

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

02

| UDI-DI / UDI-DI | Broj artikla /<br>Article number | Naziv / Name                           |
|-----------------|----------------------------------|----------------------------------------|
| +J014660154950  | 66015495                         | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960  | 66015496                         | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970  | 66015497                         | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980  | 66015498                         | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990  | 66015499                         | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000  | 66015500                         | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040  | 66015504                         | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010  | 66015501                         | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020  | 66015502                         | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450  | 66095845                         | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460  | 66095846                         | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470  | 66095847                         | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480  | 66095848                         | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490  | 66095849                         | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500  | 66095850                         | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510  | 66095851                         | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520  | 66095852                         | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530  | 66095853                         | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

23.10.2024  
Hanau,

Mjesto, datum / Place, date

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

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 orvostechnikai eszköz / the medical device **Charisma Smart**

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  
++J0141103COMP010103h8A

osztálya / of class

Ila

a következő szabály szerint / according to rule

8-1, 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 Flow, 02. verzió  
Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 02

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

02

Felváltja a megfelelőségi nyilatkozatot ettől /  
Replaces Declaration of Conformity from

29.11.2022

Hanau, 23.10.2024

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 Flow

Verziószám / *Version number*

02

Felváltja a mellékletet ettől /  
*Replaces Annex from*

29.11.2022

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

02

| UDI-DI / <i>UDI-DI</i> | Cikkszám /<br><i>Article number</i> | Név / <i>Name</i>                      |
|------------------------|-------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                            | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                            | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                            | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                            | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                            | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                            | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                            | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                            | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                            | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                            | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                            | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                            | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                            | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                            | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                            | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                            | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                            | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                            | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

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

Hely, dátum / *Place, date*

Név és funkció / *Name and function*

**DICHIARAZIONE DI CONFORMITÀ / DECLARATION OF CONFORMITY**

Nome e indirizzo della società /  
*Name and address of the company*

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

**Dichiariamo sotto la nostra esclusiva responsabilità che /  
*We declare under our sole responsibility that***

il dispositivo medico / *the medical device*

**Charisma Flow**

Nome, tipo o modello, numero di lotto o di serie,  
eventualmente fonti e numero di articoli / *Name,  
type or model, batch or serial number, possibly  
sources and number of items*

Elenco degli articoli vedi allegato / *List of Articles see Annex*

Codice EMDN / *EMDN-Code*  
Codice GMDN / *GMDN code*  
Codice UMDNS / *UMDNS code*  
UDI-DI di base / *Basic UDI-DI*

Q 010101  
35870  
16-724  
++J0141103COMP010103h8A

di classe / *of class*

Ila

secondo la norma / *according to rule*

8-1, 19-3 secondo l'allegato VIII del regolamento sui dispositivi  
medici 2017/745 / *according to Annex VIII of Medical Device  
Regulation 2017/745*

**soddisfa tutte le disposizioni del regolamento sui dispositivi medici 2017/745 ad esso applicabili. /  
*meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***

Norme armonizzate applicate, norme nazionali o  
altri documenti normativi / *Applied harmonised  
standards, national standards or other normative  
documents*

EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Ulteriori norme applicate vedi Documentazione tecnica di  
Prodotto Charisma Flow, Versione 02  
*Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 02*

Procedura di valutazione della conformità secondo il  
/ *Conformity assessment procedure acc. to*

Regolamento sui dispositivi medici 2017/745 Allegato IX, Capitolo I,  
Paragrafi 2 e 3, e Capitolo III  
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section  
2 and 3 and Chapter III*

Organismo notificato / *Notified Body*

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Norimberga / Germany

CE 0197

Numero di registrazione / *Registration number:*

HZ 1198082-1

Numero versione / *Version number*

02

Sostituisce la dichiarazione di conformità di /  
*Replaces Declaration of Conformity from*

29.11.2022

Hanau, 23.10.2024

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

Luogo, data / *Place, date*

Nome e funzione / *Name and function*

La presente dichiarazione di conformità ha validità di 2 anni in relazione ai documenti di rilascio per il lotto corrispondente di  
dispositivi prodotti. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective  
batch of produced devices.*



**Elenco degli articoli / List of Articles**  
**Allegato / Annex: Dichiarazione di conformità / Declaration of Conformity**

Il dispositivo medico /  
*The medical device*

**Charisma Flow**

Numero versione / *Version number*

02

Sostituisce l'allegato da /  
*Replaces Annex from*

29.11.2022

Questa lista di articoli è valida per la versione  
della dichiarazione di conformità / *This article  
list is valid for the declaration of conformity  
version*

02

| <b>UDI-DI / UDI-DI</b> | <b>Numero articolo /<br/>Article number</b> | <b>Nome / Name</b>                     |
|------------------------|---------------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                                    | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                                    | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                                    | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                                    | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                                    | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                                    | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                                    | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                                    | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                                    | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

23.10.2024  
Hanau,

*i.V. Dr. Matthias Hartmann*

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

Luogo, data / *Place, date*

Nome e funzione / *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 Smart**

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  
++J0141103COMP010103h8Aklasės / *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 Flow, techninėje dokumentacijoje, 2 versijoje  
*Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 2*Atitikties patvirtinimo procedūra pagal /  
*Conformity assessment procedure acc. to*Medicinos priemonių reglamento 2017/745 IX priedas, I skyrius, 2 ir  
3 straipsniai bei III skyrius*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section  
2 and 3 and Chapter III*Notifikuotoji įstaiga / *Notified Body*TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Vokietija

CE 0197

Registracijos numeris / *Registration number:*

HZ 1198082-1

Versijos numeris / *Version number*

02

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

29.11.2022

Hanau, 23.10.2024

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 Flow**

Versijos numeris / *Version number*

02

Pakeičia Priedą nuo /  
*Replaces Annex from*

29.11.2022

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

02

| <b>UDI-DI / UDI-DI</b> | <b>Prekės numeris /<br/>Article number</b> | <b>Pavadinimas / Name</b>              |
|------------------------|--------------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                                   | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                                   | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                                   | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                                   | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                                   | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                                   | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                                   | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                                   | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                                   | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                                   | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                                   | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                                   | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                                   | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                                   | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                                   | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                                   | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                                   | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                                   | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

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

Vieta, data / *Place, date*

Vardas, pavardė ir pareigos / *Name and function*

**ATBILSTĪBAS DEKLARĀCIJA / DECLARATION OF CONFORMITY**

Uzņēmuma nosaukums un adrese /  
*Name and address of the company*

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

SRN: DE-MF-000007705

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

**Charisma Flow**

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  
++J0141103COMP010103h8A

klase / *of class*

Ila

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 Flow, V2. versija  
*Further Applied standards see Technical Documentation of Product Charisma Flow, Version 2.*

Atbilstības novērtēšanas procedūra saskaņā ar /  
*Conformity assessment procedure acc. to*

Medicīnisko ierīču regulas 2017/745 IX pielikumu, I nodaļu, 2. un 3. iedaļu un III nodaļu

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

Pilnvarotā iestāde / *Notified Body*

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg/Vācija

CE 0197

Reģistrācijas numurs / *Registration number:*

HZ 1198082-1

Versijas numurs / *Version number*

02

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

29.11.2022

Hānava 23.10.2024

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 / **Charisma Flow**  
*The medical device*

Versijas numurs / *Version number* 02

Aizstāj pielikumu, kas datēts ar / 29.11.2022  
*Replaces Annex from*

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

| UDI-DI / <i>UDI-DI</i> | Preces numurs / <i>Article number</i> | Nosaukums / <i>Name</i>                |
|------------------------|---------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                              | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                              | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                              | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                              | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                              | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                              | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                              | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                              | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                              | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                              | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                              | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                              | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                              | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                              | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                              | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                              | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                              | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                              | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hānava 23.10.2024

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*

**VERKLARING VAN CONFORMITEIT / DECLARATION OF CONFORMITY**

Naam en adres van de onderneming /  
*Name and address of the company*

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

**Wij verklaren geheel onder onze eigen verantwoordelijkheid dat /  
We declare under our sole responsibility that**

het medisch hulpmiddel / *the medical device*

**Charisma Flow**

Naam, type of model, batch of serienummer,  
mogelijke bronnen en aantal items / *Name, type or  
model, batch or serial number, possibly sources and  
number of items*

Voor lijst met artikelen, zie bijlage / *List of Articles see Annex*

EMDN-code / *EMDN-Code*  
GMDN-code / *GMDN code*  
UMDNS-code / *UMDNS code*  
Basis UDI-DI / *Basic UDI-DI*

Q 010101  
35870  
16-724  
++J0141103COMP010103h8A

van klasse / *of class*

Ila

in overeenstemming met regelgeving / *according to  
rule*

8-1, 19-3 conform Bijlage VIII van de Verordening (EU) 2017/745  
betreffende medische hulpmiddelen / *according to Annex VIII of  
Medical Device Regulation 2017/745*

**voldoet aan alle voorschriften van de Verordening (EU) 2017/745 betreffende medische hulpmiddelen die erop van  
toepassing zijn. / meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.**

Toegepaste geharmoniseerde normen, nationale  
normen of andere normatieve documenten / *Applied  
harmonised standards, national standards or other  
normative documents*

EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Voor overige toegepaste normen, zie technische documenten van  
product Charisma Flow, versie 02  
*Further Applied standards see Technical Documentation of Product  
Charisma Flow, Version 02*

Conformiteitsbeoordelingsprocedure in  
overeenstemming met / *Conformity assessment  
procedure acc. to*

Verordening (EU) 2017/745 betreffende medische hulpmiddelen  
bijlage IX, hoofdstuk I, sectie 2 en 3 en hoofdstuk III  
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2  
and 3 and Chapter III*

Aangemelde instantie / *Notified Body*

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Duitsland

CE 0197

Registratienummer / *Registration number:*

HZ 1198082-1

Versienummer / *Version number*

02

Vervangt de verklaring van conformiteit van /  
*Replaces Declaration of Conformity from*

29.11.2022

Hanau, 23.10.2024

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

Plaats, datum / *Place, date*

Naam en functie / *Name and function*

Deze conformiteitsverklaring is 2 jaar geldig in verband met de vrijgavedocumenten voor de respectieve partij van geproduceerde  
hulpmiddelen / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of  
produced devices.*



## Lijst met artikelen / *List of Articles*

### Annex / *Annex: Verklaring van conformiteit / Declaration of Conformity*

Het medisch hulpmiddel /  
*The medical device*

**Charisma Flow**

Versienummer / *Version number*

02

Vervangt de bijlage van /  
*Replaces Annex from*

29.11.2022

Deze artikellijst is geldig voor de  
conformiteitsverklaring, versie / *This article  
list is valid for the declaration of conformity  
version*

02

| <b>Unieke identificatiecode /<br/>UDI-DI</b> | <b>Artikelnummer /<br/>Article number</b> | <b>Naam / Name</b>                     |
|----------------------------------------------|-------------------------------------------|----------------------------------------|
| +J014660154950                               | 66015495                                  | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960                               | 66015496                                  | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970                               | 66015497                                  | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980                               | 66015498                                  | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990                               | 66015499                                  | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000                               | 66015500                                  | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040                               | 66015504                                  | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010                               | 66015501                                  | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020                               | 66015502                                  | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450                               | 66095845                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460                               | 66095846                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470                               | 66095847                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480                               | 66095848                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490                               | 66095849                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500                               | 66095850                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510                               | 66095851                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520                               | 66095852                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530                               | 66095853                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

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

Plaats, datum / *Place, date*

Naam en functie / *Name and function*

**SAMSVARSEKLERING / DECLARATION OF CONFORMITY**Selskapets navn og adresse /  
*Name and address of the company***Kulzer GmbH**  
Leipziger Straße 2, 63450 Hanau  
Tyskland / Germany  
SRN: DE-MF-000007705**Vi erklærer på eget ansvar at / We declare under our sole responsibility that**det medisinske utstyret / *the medical device***Charisma Flow**Navn, type eller modell, parti- eller serienummer,  
eventuelt kilder og antall elementer /  
*Name, type or model, batch or serial number, possibly  
sources and number of items*Liste over artikler, se vedlegg / *List of Articles, see Annex*EMDN-kode / *EMDN-Code*  
GMDN-kode / *GMDN code*  
UMDNS-kode / *UMDNS code*  
Grunnleggende UDI-DI / *Basic UDI-DI*Q 010101  
35870  
16-724  
++J0141103COMP010103h8Ai klasse / *of class*

IIa

i henhold til regel / *according to rule*8-1, 19-3 i henhold til vedlegg VIII i forordning 2017/745 om  
medisinsk utstyr / *according to Annex VIII of Medical Device  
Regulation 2017/745***oppfyller alle relevante bestemmelser i forordning 2017/745 om medisinsk utstyr. /  
*meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***Anvendte harmoniserte standarder, nasjonale  
standarder eller andre normative dokumenter /  
*Applied harmonised standards, national standards or  
other normative documents*EN ISO 4049 - Dentistry- Polymer-based restorative materials  
Ytterligere anvendte standarder, se teknisk dokumentasjon for  
produktet Charisma Flow, versjon 02  
*Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 02*forordning 2017/745 om medisinsk utstyr vedlegg IX, kapittel I,  
avsnitt 2 og 3 og kapittel IIIProsedyre for samsvarsvurdering i henhold til /  
*Conformity assessment procedure acc. to**Medical Device Regulation 2017/745 Annex IX, Chapter I, Section  
2 and 3 and Chapter III*Teknisk kontrollorgan / *Notified Body*TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Tyskland

CE 0197

Registreringsnummer / *Registration number*

HZ 1198082-1

Versjonsnummer / *Version number*

02

Erstatter samsvarserklæring fra /  
*Replaces Declaration of Conformity from*

29.11.2022

Hanau, 23.10.2024

i.V. Dr. Matthias Hartmann  
Head of Global Quality, Regulatory & Scientific Services  
**Kulzer GmbH**Sted, dato / *Place, date*Navn og funksjon / *Name and function*

Denne samsvarserklæringen er gyldig i 2 år i tilknytning til frigivelsesdokumentene for det aktuelle partiet med produsert utstyr. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

## Liste over artikler / *List of Articles* Vedlegg / *Annex: Samsvarserklæring / Declaration of Conformity*

Det medisinske utstyret / **Charisma Flow**  
*The medical device*

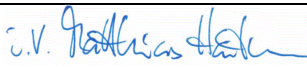
Versjonsnummer / *Version number* 02

Erstatter vedlegg fra / 29.11.2022  
*Replaces Annex from*

Denne artikkellisten gjelder for 02  
 samsvarserklæringsversjon / *This article list*  
*is valid for the declaration of conformity*  
*version*

| UDI-DI / <i>UDI-DI</i> | Artikkelnummer / <i>Article number</i> | Navn / <i>Name</i>                     |
|------------------------|----------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                               | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                               | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                               | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                               | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                               | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                               | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                               | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                               | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                               | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                               | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                               | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                               | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                               | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                               | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                               | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

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

Sted, dato / *Place, date*

Navn og funksjon / *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 Smart**

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  
++J0141103COMP010103h8A

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 Flow, wersja 02  
*Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 02*

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

Numer rejestracyjny / *Registration number:*

CE 0197  
HZ 1198082-1

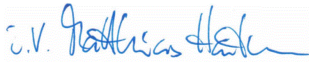
Numer wersji / *Version number*

02

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

29.11.2022

Hanau, 23.10.2024

  
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 / **Charisma Flow**  
*The medical device*

Numer wersji / *Version number* 02

Zastępuje załącznik z dnia / 29.11.2022  
*Replaces Annex from*

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

| <b>UDI-DI / UDI-DI</b> | <b>Numer wyrobu / Article number</b> | <b>Nazwa / Name</b>                    |
|------------------------|--------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                             | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                             | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                             | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                             | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                             | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                             | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                             | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                             | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                             | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                             | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                             | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                             | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                             | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                             | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                             | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                             | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                             | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                             | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

Miejscowość, data / *Place, date*

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

Imię i nazwisko, stanowisko / *Name and function*

**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-000007705Declaramos, sob nossa exclusiva responsabilidade, que / *We declare under our sole responsibility that*  
o dispositivo médico / *the medical device***Charisma Flow**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  
++J0141103COMP010103h8Ada classe / *of class*

IIa

em conformidade com o regulamento / *according to*  
*rule*8-1, 19-3 em conformidade com o Anexo VIII do Regulamento  
2017/745 relativo aos Dispositivos Médicos / *according to Annex VIII*  
*of Medical Device Regulation 2017/745***cumprir 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 Flow, Versão 02  
*Further Applied standards see Technical Documentation of*  
*Product Charisma Flow, Version 02*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*

02

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

29.11.2022

Hanau, 23.10.2024

p.p. Dr. Matthias Hartmann  
Head of Global Quality, Regulatory & Scientific Services  
**Kulzer GmbH**Local, data / *Place, date*Nome e função / *Name and function*A presente declaração de conformidade é válida durante 2 anos em associação aos documentos do respetivo lote de  
dispositivos produzidos. / *This statement of conformity is valid for 2 years in connection with the release documents for the*  
*respective batch of produced devices.*



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

O dispositivo médico /  
*The medical device*

**Charisma Flow**

Número de versão / *Version number*

02

Substitui o Anexo de /  
*Replaces Annex from*

29.11.2022

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*

02

| <b>UDI-DI / UDI-DI</b> | <b>Número de artigo /<br/>Article number</b> | <b>Nome / Name</b>                     |
|------------------------|----------------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                                     | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                                     | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                                     | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                                     | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                                     | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                                     | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                                     | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                                     | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                                     | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                                     | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                                     | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                                     | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                                     | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                                     | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                                     | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                                     | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                                     | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                                     | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

23.10.2024  
 Hanau,

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 Smart**

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*

Q 010101

Cod GMDN / *GMDN code*

35870

Cod UMDNS / *UMDNS code*

16-724

UDI-DI de bază / *Basic UDI-DI*

++J0141103COMP010103h8A

din clasa / *of class*

Ila

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 Flow, Versiunea 02  
*Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 02*

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*

02

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

29.11.2022

Hanau, 23.10.2024

i.V.

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

Loc, dată / *Place, date*

Nume și funcție / *Name and function*

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



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

Dispozitivul medical / **Charisma Flow**  
*The medical device*

Număr versiune / *Version number* 02

Înlocuiește Anexa de la / 29.11.2022  
*Replaces Annex from*

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

| <b>UDI-DI / UDI-DI</b> | <b>Număr articol / Article number</b> | <b>Nume / Name</b>                     |
|------------------------|---------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                              | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                              | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                              | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                              | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                              | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                              | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                              | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                              | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                              | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                              | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                              | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                              | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                              | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                              | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                              | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                              | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                              | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                              | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

Loc, dată / *Place, date*

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

Nume și funcție / *Name and function*

**FÖRSÄKRAN OM ÖVERENSSTÄMMELSE / DECLARATION OF CONFORMITY**Företagets namn och adress /  
*Name and address of the company***Kulzer GmbH**  
Leipziger Straße 2, 63450 Hanau  
Tyskland / Germany  
SRN: DE-MF-000007705**Vi försäkrar på eget ansvar att / We declare under our sole responsibility that**den medicintekniska produkten / *the medical device***Charisma Flow**Namn, typ eller modell, batch eller serienummer,  
eventuella källor och antal artiklar / *Name, type or  
model, batch or serial number, possibly sources and  
number of items*Se bilaga för lista över artiklar / *List of Articles see Annex*EMDN-kod / *EMDN-Code*  
GMDN-kod / *GMDN code*  
UMDNS-kod / *UMDNS code*  
Grundläggande UDI-DI / *Basic UDI-DI*Q 010101  
35870  
16-724  
++J0141103COMP010103h8Ai klass / *of class*

IIa

enligt paragraf / *according to rule*8-1, 19-3 enligt bilaga VIII i förordningen om medicintekniska  
produkter 2017/745 / *according to Annex VIII of Medical Device  
Regulation 2017/745***uppfyller kraven i förordningen om medicintekniska produkter 2017/745 som gäller produkten. /  
*meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***Tillämpade harmoniserade standarder, nationella  
standarder eller andra normerande dokument /  
*Applied harmonised standards, national standards  
or other normative documents*EN ISO 4049 - Dentistry- Polymer-based restorative materials  
För ytterligare tillämpade standarder, se teknisk dokumentation för  
produkten Charisma Flow, version 02  
*Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 02*Förfarande för bedömning av överensstämmelse  
enl. /  
*Conformity assessment procedure acc. to*förordning om medicintekniska 2017/745 bilaga IX, kapitel I,  
avsnitt 2 och 3 och kapitel III*Medical Device Regulation 2017/745 Annex IX, Chapter I,  
Section 2 and 3 and Chapter III*Anmält organ / *Notified Body*TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg/Tyskland

CE 0197

Registreringsnummer / *Registration number:*

HZ 1198082-1

Versionsnummer / *Version number*

02

Ersätter försäkran om överensstämmelse från /  
*Replaces Declaration of Conformity from*

29.11.2022

Hanau, 23.10.2024

i.V. Dr. Matthias Hartmann  
Head of Global Quality, Regulatory & Scientific Services  
**Kulzer GmbH**Ort, datum / *Place, date*Namn och funktion / *Name and function*Denna försäkran om överensstämmelse är giltig i 2 år tillsammans med dokumenten för frisläppande av respektive  
tillverkningsserie av medicintekniska produkter. / *This statement of conformity is valid for 2 years in connection with the release  
documents for the respective batch of produced devices..*



**Lista över artiklar / List of Articles**  
**Bilaga / Annex: Försäkran om överensstämmelse / Declaration of Conformity**

Den medicintekniska produkten /  
*The medical device*

**Charisma Flow**

Versionsnummer / *Version number*

02

Ersätter bilaga från /  
*Replaces Annex from*

29.11.2022

Denna artikellista gäller för förklaring av  
 överensstämmelse version / *This article list is  
 valid for the declaration of conformity version*

02

| <b>UDI-DI / UDI-DI</b> | <b>Artikelnummer /<br/>Article number</b> | <b>Namn / Name</b>                     |
|------------------------|-------------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                                  | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                                  | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                                  | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                                  | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                                  | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                                  | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                                  | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                                  | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                                  | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                                  | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

*i.V. Matthias Hartmann*

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

Ort, datum / *Place, date*

Namn och funktion / *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 Flow**

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  
++J0141103COMP010103h8A

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 Flow, različica 2.  
*Further Applied standards see Technical Documentation of Product Charisma Flow, Version 2.*

Postopek ugotavljanja skladnosti v skladu z /  
*Conformity assessment procedure acc. to*

Uredbo o medicinskih pripomočkih 2017/745, Priloga IX, poglavje I, oddelka 2 in 3, poglavje III  
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*

Priglašeni organ / *Notified Body*

TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg/Nemčija

CE 0197

Registrska številka / *Registration number:*

HZ 1198082-1

Številka različice / *Version number*

02

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

29.11.2022

Hanau, 23.10.2024

  
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 Flow**

Številka različice / *Version number*

02

Nadomešča Prilogo z dne /  
*Replaces Annex from*

29.11.2022

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

02

| UDI-DI / <i>UDI-DI</i> | Številka artikla /<br><i>Article number</i> | Ime / <i>Name</i>                      |
|------------------------|---------------------------------------------|----------------------------------------|
| +J014660154950         | 66015495                                    | CHARISMA FLOW SYR 1 X 1,8G - A1        |
| +J014660154960         | 66015496                                    | CHARISMA FLOW SYR 1 X 1,8G - A2        |
| +J014660154970         | 66015497                                    | CHARISMA FLOW SYR 1 X 1,8G - A3        |
| +J014660154980         | 66015498                                    | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
| +J014660154990         | 66015499                                    | CHARISMA FLOW SYR 1 X 1,8G - B2        |
| +J014660155000         | 66015500                                    | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                                    | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
| +J014660155010         | 66015501                                    | CHARISMA FLOW SYR 1 X 1,8G - OA2       |
| +J014660155020         | 66015502                                    | CHARISMA FLOW SYR 1 X 1,8G - OA4       |
| +J014660958450         | 66095845                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A1    |
| +J014660958460         | 66095846                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A2    |
| +J014660958470         | 66095847                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A3    |
| +J014660958480         | 66095848                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - A3,5  |
| +J014660958490         | 66095849                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - B2    |
| +J014660958500         | 66095850                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
| +J014660958510         | 66095851                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - OA2   |
| +J014660958520         | 66095852                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - OA4   |
| +J014660958530         | 66095853                                    | CHARISMA FLOW SYR ROW 1 x 1,8G - BASE  |

Hanau, 23.10.2024

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

Kraj, datum / *Place, date*

Ime in položaj / *Name and function*

**VYHLÁSENIE O ZHODE / DECLARATION OF CONFORMITY**Názov a adresa spoločnosti /  
Name and address of the company**Kulzer GmbH**  
Leipziger Straße 2, 63450 Hanau  
Nemecko / Germany

SRN: DE-MF-000007705

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

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

++J0141103COMP010103h8A

triedy / of class

IIa

podľa pravidla / according to rule

8-1, 19-3 podľa prílohy VIII k nariadeniu  
2017/745 o zdravotníckych pomôckach / according to Annex VIII  
of Medical Device Regulation 2017/745

**spĺňa všetky ustanovenia nariadenia 2017/745 o zdravotníckych pomôckach, ktoré sa na ňu vzťahujú. /**  
**meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.**

Použité harmonizované normy, národné normy  
alebo iné normatívne dokumenty / Applied  
harmonised standards, national standards or other  
normative documentsEN ISO 4049 - Dentistry- Polymer-based restorative materials  
Ďalšie použité normy nájdete v technickej dokumentácii verzie  
02 k produktu Charisma Flow  
Further Applied standards see Technical Documentation of  
Product Charisma Flow, Version 02Postup posúdenia zhody podľa /  
Conformity assessment procedure acc. toprílohy IX k nariadeniu 2017/745 o zdravotníckych pomôckach,  
kapitola I, časť 2 a 3 a kapitola IIIMedical 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

02

Nahrádza vyhlásenie o zhode z /  
Replaces Declaration of Conformity from

29.11.2022

Hanau, 23.10.2024

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 Flow**

Číslo verzie / *Version number* 02

Nahrádza prílohu z / *Replaces Annex from* 29.11.2022

Tento zoznam tovaru je platný pre vyhlásenie o zhode, verzia / *This article list is valid for the declaration of conformity version* 02

| UDI-DI / <i>UDI-DI</i> | Číslo položky / <i>Article number</i> | Meno / <i>Name</i>                     |
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| +J014660154980         | 66015498                              | CHARISMA FLOW SYR 1 X 1,8G - A3,5      |
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| +J014660155000         | 66015500                              | CHARISMA FLOW SYR 1 X 1,8G - B3        |
| +J014660155040         | 66015504                              | CHARISMA FLOW SYR 1 X 1,8G - BASELINER |
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| +J014660958500         | 66095850                              | CHARISMA FLOW SYR ROW 1 x 1,8G - B3    |
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Hanau, 23.10.2024

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

Miesto, dátum / *Place, date*

Meno a funkcia / *Name and function*