

**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**Artikelliste siehe Anhang / *List of Articles see Annex*Bezeichnung, Typ oder Modell, Chargen- oder  
Seriennummer, ev. Herkunft und Stückzahl / *Name,  
type or model, batch or serial number, possibly  
sources and number of items*EMDN-Nummer / *EMDN-Code*  
GMDN-Nummer / *GMDN code*  
UMDNS-Nummer / *UMDNS code*  
Basis-UDI-DI / *Basic UDI-DI*Q010101  
35870  
16-724  
++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 1 der Technischen  
Dokumentation von Product **Venus Flow/Charisma Flow** /  
*Further Applied standards see Technical Documentation of  
Product Venus Flow/Charisma Flow, Version 1*Konformitätsbewertungsverfahren nach /  
*Conformity assessment procedure acc. to*Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I,  
Abschnitt 2 und 3 and Kapitel III*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2  
and 3 and Chapter III*Benannte Stelle / *Notified Body*TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Germany

CE 0197

Registrierungsnr. / *Registration No.:*

HZ 1198082-1

Versionsnummer / *Version number*

1

Ersetzt Konformitätserklärung vom /  
*Replaces Declaration of Conformity from*

N/A

Hanau, Nov 29, 2022

i.V.

Dr. Matthias Hartmann  
Head of Global Quality, Regulatory & Scientific Services  
**Kulzer GmbH**Ort, Datum / *Place, date*Name und Funktion / *Name and function*

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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 / **Charisma Flow**  
 for the medical device

Versionsnummer Artikelliste/ **01**  
 Version number article list

Ersetzt Artikelliste vom / **N/A**  
 Replaces article list from

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

<b>UDI-DI / UDI-DI</b>	<b>Artikelnummer / Article number</b>	<b>Name / Name</b>
+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, Nov 29, 2022

i.V.



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

Ort, Datum / Place, date

Name und Funktion / Name and function

## 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

Q010101  
 35870  
 16-724  
 ++J0141103COMP010103h8A

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 **Venus Flow/Charisma Flow** Версия  
**1**  
 Further Applied standards see Technical Documentation of  
 Product **Venus Flow/Charisma Flow**, Version **1**

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

Регламента за медицинските изделия 2017/745 Приложение  
 IX, глава I, раздел 2 и 3 и глава III  
 Medical Device Regulation 2017/745 Annex IX, Chapter I, Section  
 2 and 3 and Chapter III

Нотифициран орган / Notified Body

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Германия  
 CE 0197

Регистрационен номер / Registration number:

HZ 1198082-1

Номер на версия / Version number

1

Заменя Декларация за съответствие от /  
 Replaces Declaration of Conformity from


N/A

Ханау, Nov 29, 2022

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

Място, дата / Place, date

Име и длъжност / Name and function



Тази Декларация за съответствие е валидна за 2 години във връзка с публикуваните документи за съответната партида произведени  
 устройства / This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced  
 devices.

**Списък с артикули / List of Articles**  
**Приложение / Annex: Декларация за съответствие / Declaration of Conformity**

Медицинското изделие / **Charisma Flow**  
*The medical device*

Номер на версия / *Version number* 01

Заменя Приложението от / *Replaces Annex from* N/A

Този списък със статии е валиден във връзка с декларацията за съответствие, версия / *This article list is valid for the declaration of conformity version* 01

UDI-DI / <i>UDI-DI</i>	Номер на артикул / <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

Ханану, Nov 29, 2022

от името на д-р



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

Място, дата / *Place, date*Име и длъжност / *Name and function*

## 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 Flow**

Název, typ nebo model, šarže nebo výrobní číslo,  
 případně zdroje a počet kusů / *Name, type or*  
*model, batch or serial number, possibly sources and*  
*number of items*

Seznam položek je uveden v příloze /  
*List of Articles see Annex*

Kód EMDN / *EMDN-Code*  
 Kód GMDN / *GMDN code*  
 Kód UMDNS / *UMDNS code*  
 Základní UDI-DI / *Basic UDI-DI*

Q010101  
 35870  
 16-724  
 ++J0141103COMP010103h8A

třídy / *of class*

Ila

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 **Venus Flow/Charisma Flow**, verze 1  
*Further Applied standards see Technical Documentation of*  
*Product Venus Flow/Charisma Flow, Version 1*

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

nařízení 2017/745 o zdravotnických prostředcích, příloha IX,  
 kapitola I, oddíl 2 a 3 a kapitola III  
*Medical Device Regulation 2017/745 Annex IX, Chapter I,*  
*Section 2 and 3 and Chapter III*

Notifikovaná osoba / *Notified Body*

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Německo

CE 0197

Registrační číslo / *Registration number:*

HZ 1198082-1

Číslo verze / *Version number*

1

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

N/A

Hanau, Nov 29, 2022

i.V.

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

Místo, datum / *Place, date*

Jméno a funkce / *Name and function*



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

## Seznam položek / *List of Articles*

### Příloha / *Annex: Prohlášení o shodě / Declaration of Conformity*

Zdravotnický prostředek / *The medical device* **Charisma Flow**


Číslo verze / *Version number* 01

Nahrazuje přílohu ze dne / *Replaces Annex from* N/A

Tento seznam zboží platí pro verzi  
prohlášení o shodě / *This article list is valid  
for the declaration of conformity version:* 01

UDI-DI / <i>UDI-DI</i>	Artikli number / <i>Article number</i>	Nimi / <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, Nov 29, 2022

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

Místo, datum / *Place, date*

Jméno a funkce / *Name and function*

## 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-00007705

**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*

Q010101  
 35870  
 16-724  
 ++J0141103COMP010103h8A

i klasse / *of class*

Ila

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 **Venus Flow/Charisma  
 Flow**, version 1  
*Further Applied standards see Technical Documentation of  
 Product Venus Flow/Charisma Flow, Version 1*

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

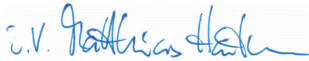
Versionsnummer / *Version number*

1

Erstatter overensstemmelseserklæring fra /  
*Replaces Declaration of Conformity from*

N/A

Hanau, Nov 29, 2022

  
 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*



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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 / <i>The medical device</i>	<b>Charisma Flow</b>
Versionsnummer / <i>Version number</i>	01
Erstatter bilag fra / <i>Replaces Annex from</i>	N/A
Denne artikelliste er gyldig i forbindelse med overensstemmelseserklæringen version / <i>This article list is valid for the declaration of conformity version</i>	01

UDI-DI / <i>UDI-DI</i>	Varenummer / <i>Article number</i>	Betegnelse / <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, Nov 29, 2022

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 Flow**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*

Q010101

GMDN-i kood / *GMDN code*

35870

UMDNS-i kood / *UMDNS code*

16-724

Põhi-UDI-DI / *Basic UDI-DI*

++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 **Venus Flow/Charisma Flow**, Version 1  
*Further Applied standards see Technical Documentation of Product Venus Flow/Charisma Flow, Version 1*Vastavushindamismenetlus vastavalt / *Conformity assessment procedure acc. to*

meditsiiniseadmete määruse 2017/745 IX. lisa, 1. 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*

1

Asendab vastavusdeklaratsiooni alates / *Replaces Declaration of Conformity from*

N/A

Hanau, Nov 29, 2022

i.V. Dr. Matthias Hartmann

Head of Global Quality, Regulatory &amp; Scientific Services

**Kulzer GmbH**Koht, kuupäev / *Place, date*Nimi ja funktsioon / *Name and function*See vastavusdeklaratsioon kehtib 2 aastat koos toodetud seadmete vastava partii väljastusdokumentidega / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

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

Meditsiiniseade / **Charisma Flow**  
 The medical device

Versiooni number / Version number 01

Asendab lisa alates / N/A  
 Replaces Annex from

See artiklite loend kehtib vastavusdeklaratsiooni 01  
 versiooni kohta / This article list is valid for the  
 declaration of conformity version

UDI-DI / UDI-DI	Artikli number / 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, Nov 29, 2022

i.V.



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

Koht, kuupäev / Place, date

Nimi ja funktsioon / Name and function

**DECLARACIÓN DE CONFORMIDAD / DECLARATION OF CONFORMITY**Nombre y dirección de la empresa /  
*Name and address of the company***Kulzer GmbH**  
Leipziger Straße 2, 63450 Hanau  
Alemania / Germany  
SRN: DE-MF-00007705Declaramos bajo nuestra exclusiva responsabilidad que / *We declare under our sole responsibility that*  
el producto sanitario / *the medical device***Charisma Flow**Nombre, tipo o modelo, lote o número de serie,  
posiblemente fuentes y número de elementos /  
*Name, type or model, batch or serial number,*  
*possibly sources and number of items*Lista de artículos en el Anexo / *List of Articles see Annex*Código EMDN / *EMDN-Code*  
Código GMDN / *GMDN code*  
Código UMDNS / *UMDNS code*  
UDI-DI básico / *Basic UDI-DI*Q010101  
35870  
16-724  
++J0141103COMP010103h8Ade la clase / *of class*

IIa

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  
materialsPara otras normas aplicadas consulte la documentación técnica del  
producto **Venus Flow/Charisma Flow**, versión 1  
*Further Applied standards see Technical Documentation of*  
*Product Venus Flow/Charisma Flow, Version 1*Procedimiento de evaluación de la conformidad de  
acuerdo con /  
*Conformity assessment procedure acc. to*Reglamento sobre productos sanitarios 2017/745 Anexo IX,  
Capítulo I, Secciones 2 y 3 y Capítulo III*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2*  
*and 3 and Chapter III*Organismo notificado / *Notified Body*TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Alemania

CE 0197

Número de registro / *Registration number:*

HZ 1198082-1

Número de versión / *Version number*

1

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

N/A

Hanau, Nov 29, 2022

i.V. Dr. Matthias Hartmann  
Head of Global Quality, Regulatory & Scientific Services  
**Kulzer GmbH**Lugar, fecha / *Place, date*Nombre y cargo / *Name and function*La presente declaración de conformidad tendrá una validez de 2 años según la documentación emitida para el correspondiente  
lote de productos fabricados. / *This statement of conformity is valid for 2 years in connection with the release documents for the*  
*respective batch of produced devices.*

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

El producto sanitario / <i>The medical device</i>	<b>Charisma Flow</b>
Número de versión / <i>Version number</i>	01
Sustituye al Anexo del / <i>Replaces Annex from</i>	N/A
Esta lista de artículos es válida para la versión de la declaración de conformidad / <i>This article list is valid for the declaration of conformity version</i>	01

<b>UDI-DI / UDI-DI</b>	<b>Número de artículo / Article number</b>	<b>Nombre / 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, Nov 29, 2022

i.V.



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

Lugar, fecha / *Place, date*

Nombre y cargo / *Name and function*

## 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

Q010101  
 35870  
 16-724  
 ++J0141103COMP010103h8A

luokka / of class

Ila

säädös / according to rule

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

**täyttää kaikki lääkinällisistä 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 **Venus Flow/Charisma Flow**, versio 1  
 Further Applied standards see Technical Documentation of  
 Product **Venus Flow/Charisma Flow**, Version 1

Vaatimustenmukaisuuden arviointimenettelyn perusta  
 /  
 Conformity assessment procedure acc. to

Asetus lääkinällisistä 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

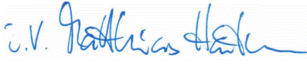
Versionumero / Version number

1

Korvaa vaatimustenmukaisuusvakuutuksen /  
 Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022

  
 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 / <i>The medical device</i>	<b>Charisma Flow</b>
Versionumero / <i>Version number</i>	01
Korvaa liitteen / <i>Replaces Annex from</i>	N/A
Tämä artikkeliluettelo pätee vaatimustenmukaisuusvakuutuksen versioon <i>/ This article list is valid for the declaration of conformity version</i>	01

<b>UDI-DI / UDI-DI</b>	<b>Artikkelinumero / Article number</b>	<b>Nimi / 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, Nov 29, 2022

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-00007705

**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*

Q010101  
 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 **Venus Flow/Charisma Flow**, version 1  
*Further Applied standards see Technical Documentation of  
 Product Venus Flow/Charisma Flow, Version 1*

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*

1

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

N/A

Hanau, Nov 29, 2022

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

Numéro de version / *Version number* 01


Remplace l'annexe de / *Replaces Annex from* N/A

Cette liste d'articles est valable pour la  
 déclaration de conformité, version / *This*  
*article list is valid for the declaration of*  
*conformity version* 01

<b>UDI-DI / UDI-DI</b>	<b>Numéro de référence / Article number</b>	<b>Nom / 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, Nov 29, 2022

Lieu, date / *Place, date*

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


---

 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 Flow**Επωνυμία, τύπος ή μοντέλο, παρτίδα ή αριθμός  
σειράς, πιθανές πηγές και αριθμός ειδών / *Name,  
type or model, batch or serial number, possibly  
sources and number of items*Κατάλογος ειδών Παράρτημα / *List of Articles see Annex*Κωδικός EMDN / *EMDN-Code*  
Κωδικός GMDN / *GMDN code*  
Κωδικός UMDNS / *UMDNS code*  
Βασικό UDI-DI / *Basic UDI-DI*Q010101  
35870  
16-724  
++J0141103COMP010103h8Aκλάσης / *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 **Venus Flow/Charisma Flow**, έκδοση 1  
*Further Applied standards see Technical Documentation of  
Product Venus Flow/Charisma Flow, Version 1*Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με  
/ *Conformity assessment procedure acc. to*Κανονισμός 2017/745 για τα ιατροτεχνολογικά προϊόντα,  
Παράρτημα IX, Κεφάλαιο I, Τμήμα 2 και 3, και Κεφάλαιο III  
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section  
2 and 3 and Chapter III*Κοινοποιημένος οργανισμός / *Notified Body*TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nürnberg / Γερμανία

CE 0197

Αριθμός καταχώρησης / *Registration number:*

HZ 1198082-1

Αριθμός έκδοσης / *Version number*

1

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

N/A

Hanau, Nov 29, 2022

i.V. Dr. Matthias Hartmann  
Head of Global Quality, Regulatory & Scientific Services  
**Kulzer GmbH**Τόπος, ημερομηνία / *Place,  
date*Όνοματεπώνυμο 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* 01

Αντικαθιστά το Παράρτημα από / *Replaces Annex from* N/A

Αυτός ο κατάλογος προϊόντων ισχύει για την έκδοση δήλωσης συμμόρφωσης / *This article list is valid for the declaration of conformity version* 01

UDI-DI / <i>UDI-DI</i>	Αριθμός είδους / <i>Article number</i>	Όνομα / <i>Name</i>
+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, Nov 29, 2022

i.V.



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

Τόπος, ημερομηνία / *Place, date*

Όνοματεπώνυμο και τίτλος / *Name and function*

## IZJAVA O USKLAĐENOSTI / *DECLARATION OF CONFORMITY*

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

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

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

medicinski proizvod / *the medical device*

**Charisma Flow**

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*  
 šifra GMDN / *GMDN code*  
 šifra UMDNS / *UMDNS code*  
 osnovni UDI-DI / *Basic UDI-DI*

Q010101  
 35870  
 16-724  
 ++J0141103COMP010103h8A

klase / *of class*

Ila

u skladu s pravilom / *according to rule*

8-1, 19-3 u skladu s Dodatkom VIII Uredbe 2017/745 o medicinskim proizvodima / *according to Annex VIII of Medical Device Regulation 2017/745*

**ispunjava sve odredbe Uredbe 2017/745 o medicinskim proizvodima koje se na njega odnose. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***

Primijenjene usklađene norme, državne norme ili drugi normativni dokumenti / *Applied harmonised standards, national standards or other normative documents*

EN ISO 4049 - Dentistry– Polymer-based restorative materials  
 Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod **Venus Flow/Charisma Flow**, verzija 1  
*Further Applied standards see Technical Documentation of Product Venus Flow/Charisma Flow, Version 1*

Postupak procjene usklađenosti prema /  
*Conformity assessment procedure acc. to*

Prilog IX Uredbi 2017/745 o medicinskim proizvodima, Poglavlje I, Odjeljak 2 i 3 te Poglavlje III  
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*

Obaviješteno tijelo / *Notified Body*

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Njemačka

CE 0197

Registracijski broj / *Registration number:*

HZ 1198082-1


Broj verzije / *Version number*

1

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

N/A

Hanau, Nov 29, 2022



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

Mjesto, datum / *Place, date*

Ime i funkcija / *Name and function*

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 / <i>The medical device</i>	<b>Charisma Flow</b>
Broj verzije / <i>Version number</i>	01
Zamjenjuje Dodatak od / <i>Replaces Annex from</i>	N/A
Ovaj popis artikala valjan je za verziju izjave u sukladnosti / <i>This article list is valid for the declaration of conformity version</i>	01

UDI-DI / <i>UDI-DI</i>	Broj artikla / <i>Article number</i>	Naziv / <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, Nov 29, 2022

i.V.

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

Mjesto, datum / *Place, date*

Ime i funkcija / *Name and function*



## MEGFELELŐSÉGI NYILATKOZAT / DECLARATION OF CONFORMITY

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

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

**Kizárólagos felelősségünkre kijelentjük, hogy / We declare under our sole responsibility that**  
 az orvostechikai eszköz / the medical device **Charisma Flow**

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

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

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

Q010101  
 35870  
 16-724  
 ++J0141103COMP010103h8A

osztálya / of class

Ila

a következő szabály szerint / according to rule

8-1, 19-3 az orvostechikai eszközökről szóló 2017/745 rendelet VIII.  
 melléklete szerint / according to Annex VIII of Medical Device  
 Regulation 2017/745

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

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

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

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

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

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

Bejelentett szervezet / Notified Body

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Németország

CE 0197

Regisztrációs szám / Registration number:

HZ 1198082-1

Verziószám / Version number

1

Felváltja a megfelelőségi nyilatkozatot ettől /  
 Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022

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

Hely, dátum / Place, date

Név és funkció / Name and function



*Ez a megfelelőségi nyilatkozat 2 évig érvényes a gyártott eszközök adott tételére vonatkozó kibocsátási dokumentumokkal együtt. / This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

## Cikkek listája / List of Articles

### Melléklet / Annex: Megfelelőségi nyilatkozat / Declaration of Conformity

Az orvostechnikai eszköz / **Charisma Flow**  
 The medical device

Verziószám / Version number 01

Felváltja a mellékletet ettől / N/A  
 Replaces Annex from

Ez a tételista a megfelelőségi nyilatkozat 01  
 következő verziójához érvényes / This article list is  
 valid for the declaration of conformity version

UDI-DI / UDI-DI	Cikkszám / Article number	Név / 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, Nov 29, 2022

i.V.

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



Hely, dátum / Place, date

Név és funkció / Name and function

## 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-00007705

**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*

Q010101  
 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 **Venus Flow/Charisma Flow** , Versione 1  
*Further Applied standards see Technical Documentation of  
 Product Venus Flow/Charisma Flow, Version 1*

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 / Germania

CE 0197

Numero di registrazione / *Registration number:*

HZ 1198082-1


Numero versione / *Version number*

1

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

N/A

Hanau, Nov 29, 2022

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

Luogo, data / *Place, date*

Nome e funzione / *Name and function*

---

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

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

Il dispositivo medico / **Charisma Flow**  
*The medical device*

Numero versione / *Version number* 01

Sostituisce l'allegato da / *N/A*  
*Replaces Annex from*

Questa lista di articoli è valida per la versione 01  
 della dichiarazione di conformità / *This article*  
*list is valid for the declaration of conformity*  
*version*

<b>UDI-DI / UDI-DI</b>	<b>Numero articolo / 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

Hanau, Nov 29, 2022

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-00007705

Prisiimdami visą atsakomybę pareiškiame, kad / We declare under our sole responsibility that  
 medicinos prietaisais / the medical device

### Charisma Flow

Pavadinimas, tipas arba modelis, partija arba serijos  
 numeris, galimi šaltiniai ir elementų skaičius / Name,  
 type or model, batch or serial number, possibly  
 sources and number of items

Prekių sąrašo ieškokite Priede / List of Articles see Annex

EMDN kodas / EMDN-Code  
 GMDN kodas / GMDN code  
 UMDNS kodas / UMDNS code  
 Pagrindinis UDI-DI / Basic UDI-DI

Q010101  
 35870  
 16-724  
 ++J0141103COMP010103h8A

klasės / of class

Ila

pagal taisyklę / according to rule

8-1, 19-3 Pagal Medicinos prietaisų reglamento 2017/745 VIII  
 priedą / according to Annex VIII of Medical Device Regulation  
 2017/745

**atitinka visas jam taikomas Medicinos prietaisų reglamento 2017/745 sąlygas. /  
 meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.**

Taikomi harmonizuotieji standartai, nacionaliniai  
 standartai ar kiti normatyviniai dokumentai / Applied  
 harmonised standards, national standards or other  
 normative documents

EN ISO 4049 - Dentistry– Polymer-based restorative  
 materials  
 atkuriamosiomis medžiagomis Kitus taikomus standartus žr.  
 produkto **Venus Flow/Charisma Flow**, techninėje  
 dokumentacijoje, 1 versijoje  
 Further Applied standards see Technical Documentation of  
 Product **Venus Flow/Charisma Flow**, Version 1

]Atitikties patvirtinimo procedūra pagal /  
 Conformity assessment procedure acc. to

Medicinos priemonių reglamento 2017/745 IX priedas, I skyrius, 2 ir  
 3 straipsniai bei III skyrius  
 Medical Device Regulation 2017/745 Annex IX, Chapter I, Section  
 2 and 3 and Chapter III

Notifikuotoji įstaiga / Notified Body

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Vokietija

CE 0197

Registracijos numeris / Registration number:

HZ 1198082-1

Versijos numeris / Version number

1

Pakeičia atitikties deklaraciją nuo /  
 Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022



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

Vieta, data / Place, date

Vardas, pavardė ir pareigos / Name and function

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



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

Medicinos prietaisas / **Charisma Flow**  
*The medical device*

Versijos numeris / *Version number* 01

Pakeičia Priedą nuo / *N/A*  
*Replaces Annex from*

Šis straipsnių sąrašas tinka atitikties deklaracijai, 01  
*kurios versija yra / This article list is valid for the*  
*declaration of conformity version*

UDI-DI / UDI-DI	Prekės numeris / Article number	Pavadinimas / 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, Nov 29, 2022

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*

Q010101  
 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 **Venus Flow/Charisma Flow** 1. versija  
 Further Applied standards see Technical Documentation of Product **Venus Flow/Charisma Flow**, Version 1

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

Medicīnisko ierīču regulas 2017/745 IX pielikumu, I nodaļu, 2. un 3. iedaļu un III nodaļu  
 Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III

Pilnvarotā iestāde / *Notified Body*

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg/Vācija

CE 0197

Reģistrācijas numurs / *Registration number*:

HZ 1198082-1

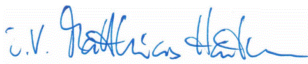
Versijas numurs / *Version number*

1

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

N/A

Hānava Nov 29, 2022

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

Vieta, datums / *Place, date*

Vārds, uzvārds un amats / *Name and function*

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



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

Medicīniskā ierīce /  
*The medical device*

**Charisma Flow**

Versijas numurs / *Version number* 01

Aizstāj pielikumu, kas datēts ar /  
*Replaces Annex from* N/A

Šis izstrādājumu saraksts ir derīgs šādai  
 atbilstības deklarācijas versijai / *This article list is*  
*valid for the declaration of conformity version* 01

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 Nov 29, 2022

v.i.

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

Vieta, datums / *Place, date*Vārds, uzvārds un amats / *Name and function*

## 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*

Q010101  
 35870  
 16-724  
 ++J0141103COMP010103h8A

van klasse / *of class*

IIa

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 **Venus Flow/Charisma Flow**, versie 1  
*Further Applied standards see Technical Documentation of Product  
 Venus Flow/Charisma Flow, Version 1*

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*

1

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

N/A

Hanau, Nov 29, 2022

  
 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 / <i>The medical device</i>	<b>Charisma Flow</b>
Versienummer / <i>Version number</i>	01
Vervangt de bijlage van / <i>Replaces Annex from</i>	N/A
Deze artikellijst is geldig voor de conformiteitsverklaring, versie / <i>This article list is valid for the declaration of conformity version</i>	01

<b>Unieke identificatiecode / UDI-DI</b>	<b>Artikelnummer / 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, Nov 29, 2022

i.V



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

Plaats, datum / *Place, date*Naam en functie / *Name and function*

**SAMSVARERKLÆRING / 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*

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35870  
16-724  
++J0141103COMP010103h8A

i klasse / *of class*

Ila

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 **Venus Flow/Charisma Flow**, versjon 1  
*Further Applied standards see Technical Documentation of  
Product Venus Flow/Charisma Flow, Version 1*

forordning 2017/745 om medisinsk utstyr vedlegg IX, kapittel I,  
avsnitt 2 og 3 og kapittel III

Prosedyre 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*

1

Erstatter samsvarserklæring fra /  
*Replaces Declaration of Conformity from*

N/A

Hanau, Nov 29, 2022

  
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* 01

Erstatter vedlegg fra / *Replaces Annex from* N/A

Denne artikkellisten gjelder for *This article list is valid for the declaration of conformity version* 01

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, Nov 29, 2022

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 Flow**

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*

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 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 **Venus Flow/Charisma Flow**, wersja 1  
*Further Applied standards see Technical Documentation of  
 Product Venus Flow/Charisma Flow, Version 1*

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

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

Jednostka notyfikowana / *Notified Body*

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg/Niemcy

CE 0197

Numer rejestracyjny / *Registration number.*

HZ 1198082-1


Numer wersji / *Version number*

1

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

N/A

Hanau, Nov 29, 2022

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

Miejscowość, data / *Place, date*

Imię i nazwisko, stanowisko / *Name and function*

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

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

Wyrób medyczny / *The medical device* **Charisma Flow**

Numer wersji / *Version number* 01

Zastępuje załącznik z dnia / *Replaces Annex from* N/A

Poniższa lista artykułów obowiązuje dla następujących wersji deklaracji zgodności / *This article list is valid for the declaration of conformity version* 01

UDI-DI / <i>UDI-DI</i>	Numer wyrobu / <i>Article number</i>	Nazwa / <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, Nov 29, 2022

i.V.



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

Miejscowość, data / *Place, date*

Imię i nazwisko, stanowisko / *Name and function*

## DECLARAÇÃO DE CONFORMIDADE / DECLARATION OF CONFORMITY

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

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

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

### Charisma 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

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 35870  
 16-724  
 ++J0141103COMP010103h8A

da classe / of class

Ila

em conformidade com o regulamento / according to  
 rule

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

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

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

EN ISO 4049 - Dentistry– Polymer-based restorative  
 materials  
 Outras normas aplicadas, ver Documentação técnica do produto  
**Venus Flow/Charisma Flow** Versão 1  
 Further Applied standards see Technical Documentation of  
 Product **Venus Flow/Charisma Flow** Version 1

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

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

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

Organismo notificado / Notified Body

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Alemanha

CE 0197

Número de registo / Registration number:

HZ 1198082-1


Número de versão / Version number

1

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

N/A

Hanau, Nov 29, 2022

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

Local, data / Place, date

Nome e função / Name and function

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



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

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

Número de versão / *Version number* 01

Substitui o Anexo de / *N/A*  
*Replaces Annex from*

A presente lista de artigos é válida para a *01*  
 versão da declaração de conformidade / *This*  
*article list is valid for the declaration of*  
*conformity version*

<b>UDI-DI / UDI-DI</b>	<b>Número de artigo / Article number</b>	<b>Nome / Name</b>
+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, Nov 29, 2022

p.p.



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

Local, data / *Place, date*

Nome e função / *Name and function*

## DECLARAȚIE DE CONFORMITATE / DECLARATION OF CONFORMITY

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

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

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

**Charisma Flow**

Nume, tip sau model, număr de lot sau de serie,  
 eventual sursele și numărul de articole / *Name,  
 type or model, batch or serial number, possibly  
 sources and number of items*

Lista de articole, vezi Anexa / *List of Articles see Annex*

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

Q010101  
 35870  
 16-724  
 ++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  
**Venus Flow/Charisma Flow**, Versiunea 1  
 Further Applied standards see Technical Documentation of  
 Product **Venus Flow/Charisma Flow** Version 1

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

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

Organism notificat / *Notified Body*

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Germania

CE 0197

Numărul de înregistrare / *Registration number*

HZ 1198082-1

Număr versiune / *Version number*

1

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

N/A

Hanau, Nov 29, 2022

i.V.

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

Loc, dată / *Place, date*

Nume și funcție / *Name and function*

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

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

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

Număr versiune / *Version number* 01

Înlocuiește Anexa de la / *N/A*  
*Replaces Annex from*

Această listă de articole este valabilă pentru *01*  
 declarația de conformitate versiunea / *This article*  
*list is valid for the declaration of conformity version*

UDI-DI / <i>UDI-DI</i>	Număr articol / <i>Article number</i>	Nume / <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, Nov 29, 2022

i.V.

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

Loc, dată / *Place, date*

Nume și funcție / *Name and function*

## 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*

Q010101  
 35870  
 16-724  
 ++J0141103COMP010103h8A

i klass / *of class*

Ila

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 **Venus Flow/Charisma Flow**, version 1  
*Further Applied standards see Technical Documentation of  
 Product Venus Flow/Charisma Flow, Version 1*

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*

1

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

N/A

Hanau, Nov 29, 2022

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

Versionsnummer / *Version number* 01

Ersätter bilaga från / *Replaces Annex from* N/A

Denna artikellista gäller för förklaring av  
 överensstämmelse version / *This article list is* 01  
 valid for the declaration of conformity version

<b>UDI-DI / UDI-DI</b>	<b>Artikelnummer / 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, Nov 29, 2022

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-00007705

**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*

Q010101  
 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 **Venus Flow/Charisma Flow**, različica 1  
*Further Applied standards see Technical Documentation of Product Venus Flow/Charisma Flow, Version 1*

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

Uredbo o medicinskih pripomočkih 2017/745, Priloga IX, poglavje I, oddelek 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*

1

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

N/A

Hanau, Nov 29, 2022

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



Kraj, datum / *Place, date*

Ime in položaj / *Name and function*

Ta izjava o skladnosti je veljavna 2 leti v povezavi z dokumenti o izdaji za zadevne serije proizvedenih pripomočkov. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

**Seznam artiklov / List of Articles**  
**Priloga / Annex: Izjava o skladnosti / Declaration of Conformity**

Medicinski pripomoček / **Charisma Flow**  
*The medical device*

Številka različice / *Version number* 01

Nadomešča Prilogo z dne / *N/A*  
*Replaces Annex from*

Ta seznam izdelkov velja za naslednjo 01  
 različico izjave o skladnosti / *This article list is*  
*valid for the declaration of conformity version*

UDI-DI / <i>UDI-DI</i>	Številka artikla / <i>Article number</i>	Ime / <i>Name</i>
+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, Nov 29, 2022

Kraj, datum / *Place, date*

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

Ime in položaj / *Name and function*

## UYHLÁSENIE 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-00007705

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

**Charisma Flow**

Názov, typ alebo model, číslo šarže alebo sériové  
 číslo, prípadne zdroje a počet kusov / *Name, type or*  
*model, batch or serial number, possibly sources and*  
*number of items*

Zoznam položiek je uvedený v prílohe / *List of Articles see Annex*

Kód EMDN / *EMDN-Code*

Q010101

Kód GMDN / *GMDN code*

35870

Kód UMDNS / *UMDNS code*

16-724

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

++J0141103COMP010103h8A

triedy / *of class*

Ila

podľa pravidiel / *according to rule*

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

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

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

EN ISO 4049 - Dentistry- Polymer-based restorative  
 materials

Ďalšie použité normy nájdete v technickej dokumentácii verzii 1 k  
 produktu **Venus Flow/Charisma Flow**  
*Further Applied standards see Technical Documentation of*  
*Product Venus Flow/Charisma Flow, Version 1*

Postup posúdenia zhody podľa /  
*Conformity assessment procedure acc. to*

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

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

Notifikovaný orgán / *Notified Body*

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Nemecko

CE 0197

Registračné číslo / *Registration number:*

HZ 1198082-1

Číslo verzie / *Version number*

1

Nahrádza vyhlásenie o zhode z /  
*Replaces Declaration of Conformity from*

N/A

Hanau, Nov 29, 2022

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

Miesto, dátum / *Place, date*

Meno a funkcia / *Name and function*

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



**Zoznam položiek / List of Articles**  
**Príloha / Annex: Vyhlásenie o zhode / Declaration of Conformity**

Zdravotnícka pomôcka / **Charisma Flow**  
*The medical device*

Číslo verzie / *Version number* 01

Nahrádza prílohu z / *N/A*  
*Replaces Annex from*

Tento zoznam tovaru je platný pre vyhlásenie o zhode, verzia / *This article list is valid for the declaration of conformity version* 01

<b>UDI-DI / UDI-DI</b>	<b>Číslo položky / Article number</b>	<b>Meno / 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, Nov 29, 2022

Miesto, dátum / *Place, date*

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

Meno a funkcia / *Name and function*

**Abschlusszertifikat**

Umschlag-ID: F6E3F09006C34E928EE326D9409BA5F5

Status: Abgeschlossen

Betreff: Mit DocuSign abschließen: Charisma Flow combined.pdf

Quellumschlag:

Dokumentenseiten: 49

Signaturen: 44

Umschlagsteller:

Zertifikatsseiten: 4

Initialen: 0

Anette Stadtfeld

Signatur mit Anleitung: Aktiviert

Leipziger Str. 2

Umschlag-ID-Stempel: Aktiviert

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**Eintragsverfolgung**

Status: Original

Inhaber: Anette Stadtfeld

Standort: DocuSign

29.11.2022 10:10:45

Anette.Stadtfeld@kulzer-dental.com

**Unterzeichnereignisse****Signatur****Zeitstempel**

Matthias Hartmann

matthias.hartmann@kulzer-dental.com

PRRC

Sicherheitsstufe: E-Mail, Kontoauthentifizierung  
(keine)

Gesendet: 29.11.2022 10:18:33

Eingesehen: 29.11.2022 12:59:58

Signiert: 29.11.2022 13:00:56

Signaturübernahme: Hochgeladenes Signaturbild  
Mit IP-Adresse: 77.181.134.104**Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:**

Akzeptiert: 29.11.2022 12:59:58

ID: 78147134-82d7-4082-b567-b12ec82c2703

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