

**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 thatdas Medizinprodukt / *the medical device***Charisma Opal 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
++J0141103COMP010103i8Cder Klasse / *of class*

IIa

nach Regel / *according to rule*8-1, 19-3 nach Anhang VIII der Medizinprodukte-Verordnung,
2017/745 / *according to Annex VIII of Medical Device Regulation
2017/745***allen Anforderungen der Medizinprodukte-Verordnung 2017/745 entspricht, die anwendbar sind /
*meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***Angewandte harmonisierte Normen, nationale
Normen oder andere normative Dokumente /
*Applied harmonised standards, national standards
or other normative documents*EN ISO 4049 - Dentistry- Polymer-based restorative materials
Weitere angewandte Normen siehe Version 03 der Technischen
Dokumentation von Product Charisma Opal Flow / *Further Applied
standards see Technical Documentation of Product Charisma
Opal Flow, Version 03*Konformitätsbewertungsverfahren nach /
*Conformity assessment procedure acc. to*Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I,
Abschnitt 2 und 3 and Kapitel III*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2
and 3 and Chapter III*Benannte Stelle / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Germany

CE 0197

Registrierungsnr. / *Registration No.:*

HZ 1198082-1

Versionsnummer / *Version number*

03

Ersetzt Konformitätserklärung vom /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

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

Artikelliste / List of Articles
Anhang zur Konformitätserklärung / Annex to declaration of conformity

das Medizinprodukt /
for the medical device

Charisma Opal Flow

Versionsnummer Artikelliste /
Version number article list

04

Ersetzt Artikelliste vom /
Replaces article list from

08.08.2024

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

UDI-DI / UDI-DI	Artikelnummer / Article number	Name / Name
+J014660409000	66040900	CHARISMA OPAL FLOW SYR 1,8G – A1
+J014660409510	66040951	CHARISMA OPAL FLOW SYR 1,8G – A2
+J014660409520	66040952	CHARISMA OPAL FLOW SYR 1,8G – A3
+J014660409530	66040953	CHARISMA OPAL FLOW SYR 1,8G – A4
+J014660409540	66040954	CHARISMA OPAL FLOW SYR 1,8G – B2
+J014660409550	66040955	CHARISMA OPAL FLOW SYR 1,8G – OM
+J014660409560	66040956	CHARISMA OPAL FLOW SYR 1,8G – BASELINER

Hanau, 21.10.2024

Ort, Datum / Place, date



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

Name und Funktion / Name and function

**ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ / DECLARATION OF CONFORMITY**

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

Kulzer GmbH
Leipziger Straße 2, 63450 Hanau
Германия / Germany

SRN: DE-MF-000007705

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

медицинското изделие / the medical device

Charisma Opal 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
++J0141103COMP010103i8C

от клас / of class

Ila

съгласно правило / according to rule

8-1, 19-3 съгласно Приложение VIII от Регламента за
медицинските изделия 2017/745 / according to Annex VIII of
Medical Device Regulation 2017/745

**отговаря на всички разпоредби на Регламента за медицинските изделия 2017/745, който се прилага за него. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.**

Приложени хармонизирани стандарти, национални
стандарти или други нормативни документи /
Applied harmonised standards, national standards or
other normative documents

EN ISO 4049 - Dentistry- Polymer-based restorative materials
Други приложени стандарти, вижте техническата
документация на продукт Charisma Opal Flow Версия 03
Further Applied standards see Technical Documentation of
Product Charisma Opal Flow, Version 03

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

03

Заменя Декларация за съответствие от /
Replaces Declaration of Conformity from

08.08.2024

Ханау, 21.10.2024

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

Място, дата / Place, date

Име и длъжност / Name and function

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

Списък с артикули / *List of Articles*

Приложение / *Annex*: Декларация за съответствие / *Declaration of Conformity*

Медицинското изделие /
The medical device

Charisma Opal Flow

Номер на версия / *Version number*

04

Заменя Приложението от /
Replaces Annex from

08.08.2024

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

03

UDI-DI / <i>UDI-DI</i>	Номер на артикул / <i>Article number</i>	Наименование / <i>Name</i>
+J014660409000	66040900	CHARISMA OPAL FLOW SYR 1,8G – A1
+J014660409510	66040951	CHARISMA OPAL FLOW SYR 1,8G – A2
+J014660409520	66040952	CHARISMA OPAL FLOW SYR 1,8G – A3
+J014660409530	66040953	CHARISMA OPAL FLOW SYR 1,8G – A4
+J014660409540	66040954	CHARISMA OPAL FLOW SYR 1,8G – B2
+J014660409550	66040955	CHARISMA OPAL FLOW SYR 1,8G – OM
+J014660409560	66040956	CHARISMA OPAL FLOW SYR 1,8G – BASELINER

Ханау, 21.10.2024

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

Място, дата / *Place, date*

Име и длъжност / *Name and function*

**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 Opal 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
++J0141103COMP010103i8C

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 Charisma Opal Flow, verze 03
Further Applied standards see Technical Documentation of
Product Charisma Opal Flow, Version 03

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

03

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

08.08.2024

Hanau, 21.10.2024

i.V.

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

Místo, datum / Place, date

Jméno a funkce / Name and function

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

Seznam položek / List of Articles
Příloha / Annex: Prohlášení o shodě / Declaration of Conformity

Zdravotnický prostředek /
The medical device

Charisma Opal Flow

Číslo verze / Version number

04

Nahrazuje přílohu ze dne /
Replaces Annex from

08.08.2024

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

03

UDI-DI / UDI-DI	Číslo zboží / Article number	Název / Name
+J014660409000	66040900	CHARISMA OPAL FLOW SYR 1,8G – A1
+J014660409510	66040951	CHARISMA OPAL FLOW SYR 1,8G – A2
+J014660409520	66040952	CHARISMA OPAL FLOW SYR 1,8G – A3
+J014660409530	66040953	CHARISMA OPAL FLOW SYR 1,8G – A4
+J014660409540	66040954	CHARISMA OPAL FLOW SYR 1,8G – B2
+J014660409550	66040955	CHARISMA OPAL FLOW SYR 1,8G – OM
+J014660409560	66040956	CHARISMA OPAL FLOW SYR 1,8G – BASELINER

Hanau, 21.10.2024


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

Místo, datum / Place, date

Jméno a funkce / Name and function

DECLARACIÓN DE CONFORMIDAD / DECLARATION OF CONFORMITY

Nombre y dirección de la empresa / <i>Name and address of the company</i>	Kulzer GmbH Leipziger Straße 2, 63450 Hanau Alemania / Germany SRN: DE-MF-000007705
Declaramos bajo nuestra exclusiva responsabilidad que / <i>We declare under our sole responsibility that</i>	
el producto sanitario / <i>the medical device</i>	Charisma Opal Flow
Nombre, tipo o modelo, lote o número de serie, posiblemente fuentes y número de elementos / <i>Name, type or model, batch or serial number, possibly sources and number of items</i>	Lista de artículos en el Anexo / <i>List of Articles see Annex</i>
Código EMDN / <i>EMDN-Code</i>	Q010101
Código GMDN / <i>GMDN code</i>	35870
Código UMDNS / <i>UMDNS code</i>	16-724
UDI-DI básico / <i>Basic UDI-DI</i>	++J0141103COMP010103i8C
de la clase / <i>of class</i>	Ila
de acuerdo con la norma / <i>according to rule</i>	8-1, 19-3 de acuerdo con el Anexo VIII del Reglamento sobre productos sanitarios 2017/745 / <i>according to Annex VIII of Medical Device Regulation 2017/745</i>
cumple todas las disposiciones del Reglamento sobre productos sanitarios 2017/745 que se le aplican. / <i>meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.</i>	
Normas armonizadas, normas nacionales u otros documentos normativos que se aplican / <i>Applied harmonised standards, national standards or other normative documents</i>	EN ISO 4049 - Dentistry– Polymer-based restorative materials Para otras normas aplicadas consulte la documentación técnica del producto Charisma Opal Flow, versión 03 <i>Further Applied standards see Technical Documentation of Product Charisma Opal Flow, Version 03</i>
Procedimiento de evaluación de la conformidad de acuerdo con / <i>Conformity assessment procedure acc. to</i>	Reglamento sobre productos sanitarios 2017/745 Anexo IX, Capítulo I, Secciones 2 y 3 y Capítulo III <i>Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III</i>
Organismo notificado / <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Alemania CE 0197
Número de registro / <i>Registration number:</i>	HZ 1198082-1
Número de versión / <i>Version number</i>	03
Sustituye a la declaración de conformidad del / <i>Replaces Declaration of Conformity from</i>	08.08.2024 
Hanau, 21.10.2024	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services Kulzer GmbH
Lugar, fecha / <i>Place, date</i>	Nombre y cargo / <i>Name and function</i>

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

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

El producto sanitario /
The medical device

Número de versión / *Version number*

Sustituye al Anexo del /
Replaces Annex from

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

Charisma Opal Flow

04

08.08.2024

03

UDI-DI / <i>UDI-DI</i>	Número de artículo / <i>Article number</i>	Nombre / <i>Name</i>
+J014660409000	66040900	CHARISMA OPAL FLOW SYR 1,8G – A1
+J014660409510	66040951	CHARISMA OPAL FLOW SYR 1,8G – A2
+J014660409520	66040952	CHARISMA OPAL FLOW SYR 1,8G – A3
+J014660409530	66040953	CHARISMA OPAL FLOW SYR 1,8G – A4
+J014660409540	66040954	CHARISMA OPAL FLOW SYR 1,8G – B2
+J014660409550	66040955	CHARISMA OPAL FLOW SYR 1,8G – OM
+J014660409560	66040956	CHARISMA OPAL FLOW SYR 1,8G – BASELINER

21.10.2024

Hanau,

Lugar, fecha / *Place, date*



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

Nombre y cargo / *Name and function*

Dok.: 2057497

Version: 01

Página 1 de 1

ES/GB

**ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ / DECLARATION OF CONFORMITY**Επωνυμία και διεύθυνση εταιρείας /
*Name and address of the company***Kulzer GmbH**
Leipziger Straße 2, 63450 Hanau
Γερμανία / Germany
SRN: DE-MF-000007705**Δηλώνουμε με δική μας ευθύνη ότι / We declare under our sole responsibility that**το ιατροτεχνολογικό προϊόν / *the medical device***Charisma Opal 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
++J0141103COMP010103i8Cκλάσης / *of class*

IIa

σύμφωνα με τον κανόνα / *according to rule*8-1, 19-3 σύμφωνα με το Παράρτημα VIII του Κανονισμού
2017/745 για τα ιατροτεχνολογικά προϊόντα / *according to Annex
VIII of Medical Device Regulation 2017/745***πληροί όλες τις ισχύουσες διατάξεις του Κανονισμού 2017/745 για τα ιατροτεχνολογικά προϊόντα. /
*meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***Εφαρμοζόμενα εναρμονισμένα πρότυπα, εθνικά
πρότυπα ή άλλα κανονιστικά έγγραφα / *Applied
harmonised standards, national standards or other
normative documents*EN ISO 4049 - Dentistry- Polymer-based restorative materials
Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική
τεκμηρίωση του
προϊόντος Charisma Opal Flow, έκδοση 03
*Further Applied standards see Technical Documentation of
Product Charisma Opal Flow, Version 03*Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με
/ *Conformity assessment procedure acc. to*Κανονισμός 2017/745 για τα ιατροτεχνολογικά προϊόντα,
Παράρτημα IX, Κεφάλαιο I, Τμήμα 2 και 3, και Κεφάλαιο III
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section
2 and 3 and Chapter III*Κοινοποιημένος οργανισμός / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Γερμανία

CE 0197

Αριθμός καταχώρησης / *Registration number:*

HZ 1198082-1

Αριθμός έκδοσης / *Version number*

03

Αντικαθιστά τη δήλωση συμμόρφωσης από /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

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

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

Το ιατροτεχνολογικό προϊόν /
The medical device

Αριθμός έκδοσης / *Version number*

Αντικαθιστά το Παράρτημα από /
Replaces Annex from

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

Charisma Opal Flow

04

08.08.2024

03

UDI-DI / <i>UDI-DI</i>	Αριθμός είδους / <i>Article number</i>	Όνομα / <i>Name</i>
+J014660409000	66040900	CHARISMA OPAL FLOW SYR 1,8G – A1
+J014660409510	66040951	CHARISMA OPAL FLOW SYR 1,8G – A2
+J014660409520	66040952	CHARISMA OPAL FLOW SYR 1,8G – A3
+J014660409530	66040953	CHARISMA OPAL FLOW SYR 1,8G – A4
+J014660409540	66040954	CHARISMA OPAL FLOW SYR 1,8G – B2
+J014660409550	66040955	CHARISMA OPAL FLOW SYR 1,8G – OM
+J014660409560	66040956	CHARISMA OPAL FLOW SYR 1,8G – BASELINER

21.10.2024
Hanau,

Τόπος, ημερομηνία / *Place, date*


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

Ονοματεπώνυμο και τίτλος / *Name and function*

**IZJAVA O USKLAĐENOSTI / DECLARATION OF CONFORMITY**Naziv i adresa tvrtke /
*Name and address of the company***Kulzer GmbH**
Leipziger Straße 2, 63450 Hanau
Njemačka / Germany
SRN: DE-MF-000007705**Izjavljujemo pod punom odgovornošću da / We declare under our sole responsibility that**medicinski proizvod / *the medical device***Charisma Opal 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
++J0141103COMP010103i8Cklase / *of class*

IIa

u skladu s pravilom / *according to rule*8-1, 19-3 u skladu s Dodatkom VIII Uredbe 2017/745 o medicinskim proizvodima / *according to Annex VIII of Medical Device Regulation 2017/745***ispunjava sve odredbe Uredbe 2017/745 o medicinskim proizvodima koje se na njega odnose. /
*meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.***Primijenjene usklađene norme, državne norme ili drugi normativni dokumenti / *Applied harmonised standards, national standards or other normative documents*EN ISO 4049 - Dentistry- Polymer-based restorative materials
Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod Charisma Opal Flow, verzija 03
*Further Applied standards see Technical Documentation of Product Charisma Opal Flow, Version 03*Postupak procjene usklađenosti prema /
*Conformity assessment procedure acc. to*Prilog IX Uredbi 2017/745 o medicinskim proizvodima, Poglavlje I, Odjeljak 2 i 3 te Poglavlje III
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*Obaviješteno tijelo / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Njemačka

CE 0197

Registracijski broj / *Registration number*

HZ 1198082-1

Broj verzije / *Version number*

03

Zamjenjuje Izjavu o usklađenosti od /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbHMjesto, datum / *Place, date*Ime i funkcija / *Name and function*

Ova Izjava o usklađenosti valjana je 2 godine u odnosu na dokumente o izdanju za odgovarajuće serije proizvedenih umedicinskih proizvoda. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Popis artikala / List of Articles
Dodatak / Annex: Izjava o usklađenosti / Declaration of Conformity

Medicinski proizvod /
The medical device

Charisma Opal Flow

Broj verzije / *Version number*

04

Zamjenjuje Dodatak od /
Replaces Annex from

08.08.2024

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

03

UDI-DI / <i>UDI-DI</i>	Broj artikla / <i>Article number</i>	Naziv / <i>Name</i>
+J014660409000	66040900	CHARISMA OPAL FLOW SYR 1,8G – A1
+J014660409510	66040951	CHARISMA OPAL FLOW SYR 1,8G – A2
+J014660409520	66040952	CHARISMA OPAL FLOW SYR 1,8G – A3
+J014660409530	66040953	CHARISMA OPAL FLOW SYR 1,8G – A4
+J014660409540	66040954	CHARISMA OPAL FLOW SYR 1,8G – B2
+J014660409550	66040955	CHARISMA OPAL FLOW SYR 1,8G – OM
+J014660409560	66040956	CHARISMA OPAL FLOW SYR 1,8G – BASELINER

Hanau, 21.10.2024

Mjesto, datum / *Place, date*


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

Ime i funkcija / *Name and function*

**MEGFELELŐSÉGI NYILATKOZAT / DECLARATION OF CONFORMITY**

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

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

Kizárólagos felelősségünkre kijelentjük, hogy / We declare under our sole responsibility that
az orvostechnikai eszköz / the medical device **Charisma Opal 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
++J0141103COMP010103i8C

osztálya / of class

Ila

a következő szabály szerint / according to rule

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

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

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

EN ISO 4049 - Dentistry- Polymer-based restorative materials
További alkalmazott szabványokat lásd a műszaki dokumentációban,
termék: Charisma Opal Flow, 03. verzió
Further Applied standards see Technical Documentation of
Product Charisma Opal Flow, Version 03

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

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

Bejelentett szervezet / Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Németország

CE 0197

Regisztrációs szám / Registration number:

HZ 1198082-1

Verziószám / Version number

03

Felváltja a megfelelőségi nyilatkozatot ettől /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

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

Hely, dátum / Place, date

Név és funkció / Name and function

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

Cikkek listája / *List of Articles*

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

Az orvostechnikai eszköz /
The medical device

Charisma Opal Flow

Verziószám / *Version number*

04

Felváltja a mellékletet ettől /
Replaces Annex from

08.08.2024

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

03

UDI-DI / <i>UDI-DI</i>	Cikkszám / <i>Article number</i>	Név / <i>Name</i>
+J014660409000	66040900	CHARISMA OPAL FLOW SYR 1,8G – A1
+J014660409510	66040951	CHARISMA OPAL FLOW SYR 1,8G – A2
+J014660409520	66040952	CHARISMA OPAL FLOW SYR 1,8G – A3
+J014660409530	66040953	CHARISMA OPAL FLOW SYR 1,8G – A4
+J014660409540	66040954	CHARISMA OPAL FLOW SYR 1,8G – B2
+J014660409550	66040955	CHARISMA OPAL FLOW SYR 1,8G – OM
+J014660409560	66040956	CHARISMA OPAL FLOW SYR 1,8G – BASELINER

Hanau, 21.10.2024

Hely, dátum / *Place, date*



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

Név és funkció / *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 Opal 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

Q010101
35870
16-724
++J0141103COMP010103i8C

klasy / of class

Ila

zgodnie z regułą / according to rule

8-1, 19-3 zgodnie z załącznikiem VIII do Rozporządzenia
2017/745 w sprawie wyrobów medycznych / according to Annex
VIII of Medical Device Regulation 2017/745

**spełnia wszystkie przepisy Rozporządzenia 2017/745 w sprawie wyrobów medycznych, które go dotyczą. / meets all
the provisions of the Medical Device Regulation 2017/745 which apply to it.**

Zastosowane normy zharmonizowane, normy krajowe
lub inne dokumenty normatywne / Applied harmonised
standards, national standards or other normative
documents

EN ISO 4049 - Dentistry- Polymer-based restorative materials
Pozostałe stosowane normy znajdują się w dokumentacji
technicznej produktu Charisma Opal Flow, wersja 03
Further Applied standards see Technical Documentation of
Product Charisma Opal Flow, Version 03

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

Rozporządzenie 2017/745 w sprawie wyrobów medycznych,
załącznik IX, rozdział I, sekcja 2 i 3 oraz rozdział III

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

Jednostka notyfikowana / Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg/Niemcy

CE 0197

Numer rejestracyjny / Registration number:

HZ 1198082-1

Numer wersji / Version number

03

Zastępuje Deklarację zgodności z /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

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

Miejscowość, data / Place, date

Imię i nazwisko, stanowisko / Name and function

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

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

Wyrób medyczny /
The medical device

Charisma Opal Flow

Numer wersji / Version number

04

Zastępuje załącznik z dnia /
Replaces Annex from

08.08.2024

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

03

UDI-DI / UDI-DI	Numer wyrobu / Article number	Nazwa / Name
+J014660409000	66040900	CHARISMA OPAL FLOW SYR 1,8G – A1
+J014660409510	66040951	CHARISMA OPAL FLOW SYR 1,8G – A2
+J014660409520	66040952	CHARISMA OPAL FLOW SYR 1,8G – A3
+J014660409530	66040953	CHARISMA OPAL FLOW SYR 1,8G – A4
+J014660409540	66040954	CHARISMA OPAL FLOW SYR 1,8G – B2
+J014660409550	66040955	CHARISMA OPAL FLOW SYR 1,8G – OM
+J014660409560	66040956	CHARISMA OPAL FLOW SYR 1,8G – BASELINER

Hanau, 21.10.2024


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

Miejscowość, data / Place, date

Imię i nazwisko, stanowisko / Name and function

**DECLARAȚIE DE CONFORMITATE / DECLARATION OF CONFORMITY**

Numele și adresa companiei /
Name and address of the company

Kulzer GmbH
Leipziger Straße 2, 63450 Hanau
Germania / Germany

SRN: DE-MF-000007705

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

dispozitivul medical / the medical device

Charisma Opal 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

Q010101

Cod GMDN / GMDN code

35870

Cod UMDNS / UMDNS code

16-724

UDI-DI de bază / Basic UDI-DI

++J0141103COMP010103i8C

din clasa / of class

Ila

în conformitate cu regula / according to rule

8-1, 19-3 conform Anexei VIII la Regulamentul privind dispozitivele
medicale 2017/745 / according to Annex VIII of Medical Device
Regulation 2017/745

**respectă toate prevederile Regulamentului privind dispozitivele medicale 2017/745 corespunzător. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.**

Standarde armonizate, naționale aplicate sau alte
documente normative / Applied harmonised
standards, national standards or other normative
documents

EN ISO 4049 - Dentistry- Polymer-based restorative materials
Alte standarde aplicate, vezi documentația tehnică a Produsului
Charisma Opal Flow, Versiunea 03
Further Applied standards see Technical Documentation of
Product Charisma Opal Flow, Version 03

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

Regulamentul privind dispozitivele medicale 2017/745, Anexa IX,
Capitolul I, Secțiunile 2 și 3, și Capitolul III

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

Organism notificat / Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Germania

CE 0197

Numărul de înregistrare / Registration number:

HZ 1198082-1

Număr versiune / Version number

03

Înlocuiește Declarația de conformitate din /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

i.V.


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

Loc, dată / Place, date

Nume și funcție / Name and function

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

Listă de articole / *List of Articles*

Anexă / *Annex: Declarație de conformitate / Declaration of Conformity*

Dispozitivul medical /
The medical device

Charisma Opal Flow

Număr versiune / *Version number*

04

Înlocuiește Anexa de la /
Replaces Annex from

08.08.2024

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

03

UDI-DI / <i>UDI-DI</i>	Număr articol / <i>Article number</i>	Nume / <i>Name</i>
+J014660409000	66040900	CHARISMA OPAL FLOW SYR 1,8G – A1
+J014660409510	66040951	CHARISMA OPAL FLOW SYR 1,8G – A2
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+J014660409530	66040953	CHARISMA OPAL FLOW SYR 1,8G – A4
+J014660409540	66040954	CHARISMA OPAL FLOW SYR 1,8G – B2
+J014660409550	66040955	CHARISMA OPAL FLOW SYR 1,8G – OM
+J014660409560	66040956	CHARISMA OPAL FLOW SYR 1,8G – BASELINER

Hanau, 21.10.2024

Loc, dată / *Place, date*



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

Nume și funcție / *Name and function*

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

SRN: DE-MF-000007705

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

++J0141103COMP010103i8C

triedy / of class

IIa

podľa pravidla / according to rule

8-1, 19-3 podľa prílohy VIII k nariadeniu
2017/745 o zdravotníckych pomôckach / according to Annex VIII
of Medical Device Regulation 2017/745**spĺňa všetky ustanovenia nariadenia 2017/745 o zdravotníckych pomôckach, ktoré sa na ňu vzťahujú. /**
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.Použité harmonizované normy, národné normy
alebo iné normatívne dokumenty / Applied
harmonised standards, national standards or other
normative documentsEN ISO 4049 - Dentistry- Polymer-based restorative materials
Ďalšie použité normy nájdete v technickej dokumentácii verzie
03 k produktu Charisma Opal Flow
Further Applied standards see Technical Documentation of
Product Charisma Opal Flow, Version 03Postup posúdenia zhody podľa /
Conformity assessment procedure acc. toprílohy IX k nariadeniu 2017/745 o zdravotníckych pomôckach,
kapitola I, časť 2 a 3 a kapitola III*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section
2 and 3 and Chapter III*

Notifikovaný orgán / Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Nemecko

CE 0197

Registračné číslo / Registration number:

HZ 1198082-1

Číslo verzie / Version number

03

Nahrádza vyhlásenie o zhode z /
Replaces Declaration of Conformity from

08.08.2024

Hanau, 21.10.2024

i.V.

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

Miesto, dátum / Place, date

Meno a funkcia / Name and function

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

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

Zdravotnícka pomôcka /
The medical device

Charisma Opal Flow

Číslo verzie / Version number

04

Nahrádza prílohu z /
Replaces Annex from

08.08.2024

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

03

UDI-DI / UDI-DI	Číslo položky / Article number	Meno / Name
+J014660409000	66040900	CHARISMA OPAL FLOW SYR 1,8G – A1
+J014660409510	66040951	CHARISMA OPAL FLOW SYR 1,8G – A2
+J014660409520	66040952	CHARISMA OPAL FLOW SYR 1,8G – A3
+J014660409530	66040953	CHARISMA OPAL FLOW SYR 1,8G – A4
+J014660409540	66040954	CHARISMA OPAL FLOW SYR 1,8G – B2
+J014660409550	66040955	CHARISMA OPAL FLOW SYR 1,8G – OM
+J014660409560	66040956	CHARISMA OPAL FLOW SYR 1,8G – BASELINER

Hanau, 21.10.2024


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

Miesto, dátum / Place, date

Meno a funkcia / Name and function

Abschlusszertifikat

Umschlag-ID: D95E7659F70746E1BEE1D6DC67B9BFDE		Status: Abgeschlossen
Betreff: Mit Docusign abschließen: Charisma Opal Flow_MDR_DoC_V03_2024-10-xx_Annex_V04_2024-10-xx.pdf		
Quellumschlag:		
Dokumentenseiten: 20	Signaturen: 20	Umschlagsteller:
Zertifikatsseiten: 1	Initialen: 0	Daniela Wienhold
Signatur mit Anleitung: Aktiviert		Leipziger Str. 2
Umschlag-ID-Stempel: Aktiviert		Hanau, Hessen 63450
Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien		Daniela.Wienhold@kulzer-dental.com
		IP-Adresse: 52.233.243.152

Eintragsverfolgung

Status: Original	Inhaber: Daniela Wienhold	Standort: DocuSign
18.10.2024 13:38:57	Daniela.Wienhold@kulzer-dental.com	

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

Matthias Hartmann		Gesendet: 18.10.2024 13:46:29
matthias.hartmann@kulzer-dental.com		Eingesehen: 21.10.2024 09:03:01
Head of Global Quality, Regulatory & Scientific Services		Signiert: 21.10.2024 09:03:20
Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	Signaturübernahme: Hochgeladenes Signaturbild Mit IP-Adresse: 77.186.183.50	

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:
Nicht über DocuSign angeboten

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

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

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

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

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

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

Anette Stadtfeld	Kopiert	Gesendet: 18.10.2024 13:46:29
Anette.Stadtfeld@kulzer-dental.com		Eingesehen: 22.10.2024 09:18:57
Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)		

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:
Nicht über DocuSign angeboten

Zeugen-Ereignisse	Signatur	Zeitstempel
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Notarereignisse	Signatur	Zeitstempel
-----------------	----------	-------------

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

Umschlag gesendet	Hash-codiert/verschlüsselt	18.10.2024 13:46:29
Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	21.10.2024 09:03:01
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	21.10.2024 09:03:20
Abgeschlossen	Sicherheitsprüfung ausgeführt	21.10.2024 09:03:20

Zahlungen	Status	Zeitstempel
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