KULZER
MITSUI CHEMICALS GROUP

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 Bulk Flow ONE**
Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl / *Name, type or model, batch or serial number, possibly sources and number of items*	Artikelliste siehe Anhang / *List of Articles see Annex*
EMDN-Nummer / *EMDN-Code* GMDN-Nummer / *GMDN code* UMDNS-Nummer / *UMDNS code* Basis-UDI-DI / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
der 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 01 der Technischen Dokumentation von Product Charisma Bulk Flow ONE / *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Konformitätsbewertungsverfahren nach / *Conformity assessment procedure acc. to*	Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I, Abschnitt 2 und 3 and Kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Benannte Stelle / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Germany CE 0197
Registrierungsnr. / *Registration No.*:	HZ 1198082-1
Versionsnummer / *Version number*	01
Ersetzt Konformitätserklärung vom / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 2022 Ort, Datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Name und Funktion / *Name and function*

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.*

KULZER
MITSUI CHEMICALS GROUP

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

das Medizinprodukt / *for the medical device*	**Charisma Bulk Flow ONE**
Versionsnummer Artikelliste/ *Version number article list*	02
Ersetzt Artikelliste vom / *Replaces article list from*	V01, 08.02.2022
Diese Artikelliste ist gültig für die Konformitätserklärung Version/ *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hanau, Nov 22, 2022

Ort, Datum / *Place, date*

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

Name und Funktion / *Name and function*

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 Bulk Flow ONE**
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*	Q 010101
Код по GMDN / *GMDN code*	35870
Код по UMDNS / *UMDNS code*	16-724
Основна UDI-DI идентификация / *Basic UDI-DI*	++J0141103COMP010103i8C
от клас / *of class*	IIa
съгласно правило / *according to rule*	8-1, 19-3 съгласно Приложение VIII от Регламента за медицинските изделия 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Приложени хармонизирани стандарти, национални стандарти или други нормативни документи / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Други приложени стандарти, вижте техническата документация на продукт Charisma Bulk Flow ONE Версия 01 *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
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*	01
Заменя Декларация за съответствие от / *Replaces Declaration of Conformity from*	08.02.2022
Ханау, Aug 16, 2022 Място, дата / *Place, date*	от името на д-р Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Име и длъжност / *Name and function*

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 Bulk Flow ONE**
Номер на версия / *Version number*	01
Заменя Приложението от / *Replaces Annex from*	V01, 08.02.2022
Този списък със статии е валиден във връзка с декларацията за съответствие, версия / This This *article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Номер на артикул / *Article number***	**Наименование / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Ханау, Nov 22, 2022

Място, дата / *Place, date*

i.V. Matthias Hartmann

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

Име и длъжност / *Name and function*

PROHLÁŠENÍ O SHODĚ / *DECLARATION OF CONFORMITY*

Název a adresa společnosti / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Německo / *Germany* *SRN: DE-MF-000007705*

Prohlašujeme na svou výlučnou zodpovědnost, že / *We declare under our sole responsibility that*

zdravotnický prostředek / *the medical device*	**Charisma Bulk Flow ONE**
Název, typ nebo model, šarže nebo výrobní číslo, případně zdroje a počet kusů / *Name, type or model, batch or serial number, possibly sources and number of items*	Seznam položek je uveden v příloze / *List of Articles see Annex*
Kód EMDN / *EMDN-Code* Kód GMDN / *GMDN code* Kód UMDNS / *UMDNS code* Základní UDI-DI / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
třídy / *of class*	Iia
podle pravidla / *according to rule*	8-1, 19-3 podle přílohy VIII k nařízení 2017/745 o zdravotnických prostředcích / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Použité harmonizované normy, národní normy nebo jiné normativní dokumenty / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Další použité normy najdete v technické dokumentaci k výrobku Charisma Bulk Flow ONE, verze 01 *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Procedura posouzení shody podle / *Conformity assessment procedure acc. to*	nařízení 2017/745 o zdravotnických prostředcích, příloha IX, kapitola I, oddíl 2 a 3 a kapitola III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikovaná osoba / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Německo CE 0197
Registrační číslo / *Registration number*:	HZ 1198082-1
Číslo verze / *Version number*	01
Nahrazuje Prohlášení o shodě ze dne / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 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 Bulk Flow ONE**
Číslo verze / *Version number*	02
Nahrazuje přílohu ze dne / *Replaces Annex from*	V01, 08.02.2022
Tento seznam zboží platí pro verzi prohlášení o shodě / *This article list is valid for the declaration of conformity version:*	01

UDI-DI / *UDI-DI*	**Číslo zboží / *Article number***	**Název / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

i.V.

Hanau, Nov 22, 2022

Místo, datum / *Place, date*

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

Jméno a funkce / *Name and function*

VASTAVUSDEKLARATSIOON / *DECLARATION OF CONFORMITY*

Ettevõtte nimi ja aadress / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Saksamaa / *Germany* *SRN: DE-MF-000007705*

Ettevõte kinnitab oma ainuvastusel, et / *We declare under our sole responsibility that*

meditsiiniseade / *the medical device*	**Charisma Bulk Flow ONE**
Nimi, tüüp või mudel, partii või seerianumber, võimalikud allikad ja osad / *Name, type or model, batch or serial number, possibly sources and number of items*	Artiklite loendit vt lisast / *List of Articles see Annex*
EMDN-kood / *EMDN-Code* GMDN-i kood / *GMDN code* UMDNS-i kood / *UMDNS code* Põhi-UDI-DI / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
klassil / *of class*	Iia
kooskõlas reegliga / *according to rule*	8-1, 19-3 kooskõlas meditsiiniseadme määrusega 2017/745 lisaga VIII / *according to Annex VIII of Medical Device Regulation 2017/745*

vastab kõigile meditsiiniseadme määruse 2017/745 sätetele, mis seadmele kohaldub. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Kehtivad harmoniseeritud standardid, riiklikud standardid ja muud normatiivdokumendid / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Muid rakenduvaid standardeid vt tehnilistest dokumentidest tootele Charisma Bulk Flow ONE, Version 01 *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Vastavushindamismenetlus vastavalt / *Conformity assessment procedure acc. to*	meditsiiniseadmete määruse 2017/745 IX. lisa, I. peatükk, 2. ja 3. jaotis ning III. peatükk *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Teavitatud asutus / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Saksamaa CE 0197
Registreerimisnumber / *Registration number*:	HZ 1198082-1
Versiooni number / *Version number*	01
Asendab vastavusdeklaratsiooni alates / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 2022 Koht, kuupäev / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nimi ja funktsioon / *Name and function*

See vastavusdeklaratsioon kehtib 2 aastat koos toodetud seadmete vastava partii väljastusdokumentidega / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

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

Meditsiiniseade / *The medical device*	**Charisma Bulk Flow ONE**
Versiooni number / *Version number*	02
Asendab lisa alates / *Replaces Annex from*	V01, 08.02.2022
See artiklite loend kehtib vastavusdeklaratsiooni versiooni kohta / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikli number / *Article number***	**Nimi / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hanau, Nov 22, 2022

Koht, kuupäev / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH
Nimi ja funktsioon / *Name and function*

DECLARACIÓN DE CONFORMIDAD / *DECLARATION OF CONFORMITY*

Nombre y dirección de la empresa / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Alemania / *Germany* *SRN: DE-MF-000007705*

Declaramos bajo nuestra exclusiva responsabilidad que / *We declare under our sole responsibility that*

el producto sanitario / *the medical device*	**Charisma Bulk Flow ONE**
Nombre, tipo o modelo, lote o número de serie, posiblemente fuentes y número de elementos / *Name, type or model, batch or serial number, possibly sources and number of items*	Lista de artículos en el Anexo / *List of Articles see Annex*
Código EMDN / *EMDN-Code* Código GMDN / *GMDN code* Código UMDNS / *UMDNS code* UDI-DI básico / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
de 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 materials Para otras normas aplicadas consulte la documentación técnica del producto Charisma Bulk Flow ONE, versión 01 *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Procedimiento de evaluación de la conformidad de acuerdo con / *Conformity assessment procedure acc. to*	Reglamento sobre productos sanitarios 2017/745 Anexo IX, Capítulo I, Secciones 2 y 3 y Capítulo III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organismo notificado / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Alemania CE 0197
Número de registro / *Registration number*:	HZ 1198082-1
Número de versión / *Version number*	01
Sustituye a la declaración de conformidad del / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 2022 Lugar, fecha / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nombre y cargo / *Name and function*

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

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

El producto sanitario / *The medical device*	**Charisma Bulk Flow ONE**
Número de versión / *Version number*	02
Sustituye al Anexo del / *Replaces Annex from*	V01, 08.02.2022
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*	01

UDI-DI / *UDI-DI*	**Número de artículo / *Article number***	**Nombre / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hanau, Nov 22, 2022

Lugar, fecha / *Place, date*

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

Nombre y cargo / *Name and function*

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ / *DECLARATION OF CONFORMITY*

Επωνυμία και διεύθυνση εταιρείας / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Γερμανία / *Germany* *SRN: DE-MF-000007705*

Δηλώνουμε με δική μας ευθύνη ότι / *We declare under our sole responsibility that*

το ιατροτεχνολογικό προϊόν / *the medical device*	**Charisma Bulk Flow ONE**
Επωνυμία, τύπος ή μοντέλο, παρτίδα ή αριθμός σειράς, πιθανές πηγές και αριθμός ειδών / *Name, type or model, batch or serial number, possibly sources and number of items*	Κατάλογος ειδών Παράρτημα / *List of Articles see Annex*
Κωδικός EMDN / *EMDN-Code* Κωδικός GMDN / *GMDN code* Κωδικός UMDNS / *UMDNS code* Βασικό UDI-DI / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
κλάσης / *of class*	IIa
σύμφωνα με τον κανόνα / *according to rule*	8-1, 19-3 σύμφωνα με το Παράρτημα VIII του Κανονισμού 2017/745 για τα ιατροτεχνολογικά προϊόντα / *according to Annex VIII of Medical Device Regulation 2017/745*

πληροί όλες τις ισχύουσες διατάξεις του Κανονισμού 2017/745 για τα ιατροτεχνολογικά προϊόντα. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Εφαρμοζόμενα εναρμονισμένα πρότυπα, εθνικά πρότυπα ή άλλα κανονιστικά έγγραφα / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική τεκμηρίωση του προϊόντος Charisma Bulk Flow ONE, έκδοση 01 *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με / *Conformity assessment procedure acc. to*	Κανονισμός 2017/745 για τα ιατροτεχνολογικά προϊόντα, Παράρτημα IX, Κεφάλαιο I, Τμήμα 2 και 3, και Κεφάλαιο III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Κοινοποιημένος οργανισμός / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Γερμανία CE 0197
Αριθμός καταχώρησης / *Registration number*:	HZ 1198082-1
Αριθμός έκδοσης / *Version number*	01
Αντικαθιστά τη δήλωση συμμόρφωσης από / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 2022 Τόπος, ημερομηνία / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Ονοματεπώνυμο και τίτλος / *Name and function*

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 Bulk Flow ONE**
Αριθμός έκδοσης / *Version number*	02
Αντικαθιστά το Παράρτημα από / *Replaces Annex from*	V01, 08.02.2022
Αυτός ο κατάλογος προϊόντων ισχύει για την έκδοση δήλωσης συμμόρφωσης / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Αριθμός είδους / *Article number***	**Όνομα / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hanau, Nov 22, 2022

Τόπος, ημερομηνία / *Place, date*

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

Ονοματεπώνυμο και τίτλος / *Name and function*

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 Bulk Flow ONE**
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*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
klase / *of class*	IIa
u skladu s pravilom / *according to rule*	8-1, 19-3 u skladu s Dodatkom VIII Uredbe 2017/745 o medicinskim proizvodima / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Primijenjene usklađene norme, državne norme ili drugi normativni dokumenti / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod Charisma Bulk Flow ONE, verzija 01 *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Postupak procjene usklađenosti prema / *Conformity assessment procedure acc. to*	Prilog IX Uredbi 2017/745 o medicinskim proizvodima, Poglavlje I, Odjeljak 2 i 3 te Poglavlje III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Obaviješteno tijelo / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Njemačka CE 0197
Registracijski broj / *Registration number*:	HZ 1198082-1
Broj verzije / *Version number*	01
Zamjenjuje Izjavu o usklađenosti od / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 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 / *The medical device*	**Charisma Bulk Flow ONE**
Broj verzije / *Version number*	02
Zamjenjuje Dodatak od / *Replaces Annex from*	V01, 08.02.2022
Ovaj popis artikala valjan je za verziju izjave u sukladnosti / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Broj artikla / *Article number***	**Naziv / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hanau, Nov 22, 2022

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 Bulk Flow ONE**
Név, típus vagy modell, tétel vagy sorozatszám, esetleg források és tételek száma / *Name, type or model, batch or serial number, possibly sources and number of items*	A cikkek listáját lásd a mellékletben / *List of Articles see Annex*
EMDN kód / *EMDN-Code* GMDN kód / *GMDN code* UMDNS kód / *UMDNS code* Alapvető UDI-DI / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
osztálya / *of class*	IIa
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 Bulk Flow ONE, 01. verzió *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Megfelelőségértékelési eljárás a következő szerint /*Conformity assessment procedure acc. to*	Az orvostechnikai eszközökről szóló, 2017/745 rendelet IX. függeléke, az I. fejezet 2. és 3. szakasza, és a III. fejezet *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Bejelentett szervezet / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Németország CE 0197
Regisztrációs szám / *Registration number*:	HZ 1198082-1
Verziószám / *Version number*	01
Felváltja a megfelelőségi nyilatkozatot ettől / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 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 / *The medical device*	**Charisma Bulk Flow ONE**
Verziószám / *Version number*	02
Felváltja a mellékletet ettől / *Replaces Annex from*	V01, 08.02.2022
Ez a tétellista a megfelelőségi nyilatkozat következő verziójához érvényes / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Cikkszám / *Article number***	**Név / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hanau, Nov 22, 2022

Hely, dátum / *Place, date*

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

Név és funkció / *Name and function*

ATITIKTIES DEKLARACIJA / *DECLARATION OF CONFORMITY*

Bendrovės pavadinimas ir adresas / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Vokietija / *Germany* *SRN: DE-MF-000007705*

Prisiimdami visą atsakomybę pareiškiame, kad / *We declare under our sole responsibility that*

medicinos prietaisas / *the medical device*	**Charisma Bulk Flow ONE**
Pavadinimas, tipas arba modelis, partija arba serijos numeris, galimi šaltiniai ir elementų skaičius / *Name, type or model, batch or serial number, possibly sources and number of items*	Prekių sąrašo ieškokite Priede / *List of Articles see Annex*
EMDN kodas / *EMDN-Code* GMDN kodas / *GMDN code* UMDNS kodas / *UMDNS code* Pagrindinis UDI-DI / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
klasės / *of class*	Iia
pagal taisyklę / *according to rule*	8-1, 19-3 Pagal Medicinos prietaisų reglamento 2017/745 VIII priedą / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Taikomi harmonizuotieji standartai, nacionaliniai standartai ar kiti normatyviniai dokumentai / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials atkuriamosiomis medžiagomis Kitus taikomus standartus žr. produkto Charisma Bulk Flow ONE, techninėje dokumentacijoje, 01 versijoje *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Atitikties patvirtinimo procedūra pagal / *Conformity assessment procedure acc. to*	Medicinos priemonių reglamento 2017/745 IX priedas, I skyrius, 2 ir 3 straipsniai bei III skyrius *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikuotoji įstaiga / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Vokietija CE 0197
Registracijos numeris / *Registration number*:	HZ 1198082-1
Versijos numeris / *Version number*	01
Pakeičia atitikties deklaraciją nuo / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 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.*

KULZER
MITSUI CHEMICALS GROUP

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

Medicinos prietaisas / *The medical device*	**Charisma Bulk Flow ONE**
Versijos numeris / *Version number*	02
Pakeičia Priedą nuo / *Replaces Annex from*	V01, 08.02.2022
Šis straipsnių sąrašas tinka atitikties deklaracijai, kurios versija yra / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Prekės numeris / *Article number***	**Pavadinimas / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hanau, Nov 22, 2022

Vieta, data / *Place, date*

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

Vardas, pavardė ir pareigos / *Name and function*

ATBILSTĪBAS DEKLARĀCIJA / *DECLARATION OF CONFORMITY*

Uzņēmuma nosaukums un adrese / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Vācija / *Germany* *SRN: DE-MF-000007705*

Mēs vienīgi uz savu atbildību deklarējam, ka / *We declare under our sole responsibility that*

medicīniskā ierīce / *the medical device*	**Charisma Bulk Flow ONE**
Preču nosaukums, tips vai modelis, partijas vai sērijas numurs, iespējamie avoti un skaits / *Name, type or model, batch or serial number, possibly sources and number of items*	Preču sarakstu skatiet pielikumā / *List of Articles see Annex*
EMDN kods / *EMDN-Code* GMDN kods / *GMDN code* UMDNS kods / *UMDNS code* Pamata UDI-DI / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
klase / *of class*	Iia
saskaņā ar noteikumu / *according to rule*	8-1, 19-3 saskaņā ar Medicīnisko ierīču regulas 2017/745 VIII pielikumu / *according to Annex VIII of Medical Device Regulation 2017/745*

atbilst visiem tiem Medicīnisko ierīču regulas 2017/745 noteikumiem, kas uz to attiecas. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Izmantotie saskaņotie standarti, nacionālie standarti vai citi normatīvie dokumenti / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Citus izmantotos standartus skatiet tehniskajā dokumentācijā par produktu Charisma Bulk Flow ONE, 01. versija *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Atbilstības novērtēšanas procedūra saskaņā ar / *Conformity assessment procedure acc. to*	Medicīnisko ierīču regulas 2017/745 IX pielikumu, I nodaļu, 2. un 3. iedaļu un III nodaļu *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Pilnvarotā iestāde / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Vācija CE 0197
Reģistrācijas numurs / *Registration number*:	HZ 1198082-1
Versijas numurs / *Version number*	01
Aizstāj atbilstības deklarāciju, kas datēta ar / *Replaces Declaration of Conformity from*	08.02.2022
Hānava Aug 16, 2022 Vieta, datums / *Place, date*	i.V. v.i. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** 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 Bulk Flow ONE**
Versijas numurs / *Version number*	02
Aizstāj pielikumu, kas datēts ar / *Replaces Annex from*	V01, 08.02.2022
Šis izstrādājumu saraksts ir derīgs šādai atbilstības deklarācijas versijai / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Preces numurs / *Article number***	**Nosaukums / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hānava Nov 22, 2022

Vieta, datums / *Place, date*

i.V.

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

Vārds, uzvārds un amats / *Name and function*

DEKLARACJA ZGODNOŚCI / *DECLARATION OF CONFORMITY*

Nazwa i adres firmy / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Niemcy / *Germany* *SRN: DE-MF-000007705*

Niniejszym deklarujemy pod rygorem odpowiedzialności, że /
We declare under our sole responsibility that

wyrób medyczny / *the medical device*	**Charisma Bulk Flow ONE**
Nazwa, typ lub model, numer partii lub serii, ewentualnie źródła i liczba elementów / *Name, type or model, batch or serial number, possibly sources and number of items*	Wykaz wyrobów znajduje się w załączniku / *List of Articles see Annex*
Kod wyrobu wg EMDN / *EMDN-Code* Kod wyrobu wg GMDN / *GMDN code* Kod wyrobu wg UMDNS / *UMDNS code* Kod Basic UDI-DI / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
klasy / *of class*	IIa
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 Bulk Flow ONE, wersja 01 *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Procedura oceny zgodności wg. / *Conformity assessment procedure acc. to*	Rozporządzenie 2017/745 w sprawie wyrobów medycznych, załącznik IX, rozdział I, sekcja 2 i 3 oraz rozdział III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Jednostka notyfikowana / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Niemcy CE 0197
Numer rejestracyjny / *Registration number*:	HZ 1198082-1
Numer wersji / *Version number*	01
Zastępuje Deklarację zgodności z / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 2022 Miejscowość, data / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Imię i nazwisko, stanowisko / *Name and function*

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 Bulk Flow ONE**
Numer wersji / *Version number*	02
Zastępuje załącznik z dnia / *Replaces Annex from*	V01, 08.02.2022
Poniższa lista artykułów obowiązuje dla następujących wersji deklaracji zgodności / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Numer wyrobu / *Article number***	**Nazwa / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hanau, Nov 22, 2022

Miejscowość, data / *Place, date*

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

Imię i nazwisko, stanowisko / *Name and function*

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 Bulk Flow ONE**
Nume, tip sau model, număr de lot sau de serie, eventual sursele și numărul de articole / *Name, type or model, batch or serial number, possibly sources and number of items*	Lista de articole, vezi Anexa / *List of Articles see Annex*
Cod EMDN / *EMDN-Code* Cod GMDN / *GMDN code* Cod UMDNS / *UMDNS code* UDI-DI de bază / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
din clasa / *of class*	Iia
în conformitate cu regula / *according to rule*	8-1, 19-3 conform Anexei VIII la Regulamentul privind dispozitivele medicale 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Standarde armonizate, naționale aplicate sau alte documente normative / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Alte standarde aplicate, vezi documentația tehnică a Produsului Charisma Bulk Flow ONE, Versiunea 01 *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
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*	01
Înlocuiește Declarația de conformitate din / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 2022 Loc, dată / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** 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 Bulk Flow ONE**
Număr versiune / *Version number*	02
Înlocuiește Anexa de la / *Replaces Annex from*	V01, 08.02.2022
Această listă de articole este valabilă pentru declarația de conformitate versiunea / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Număr articol / *Article number***	**Nume / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Nov 22, 2022
Hanau,

Loc, dată / *Place, date*

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

Nume și funcție / *Name and function*

IZJAVA O SKLADNOSTI / *DECLARATION OF CONFORMITY*

Ime in naslov podjetja / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Nemčija / *Germany* *SRN: DE-MF-000007705*

Z izključno odgovornostjo izjavljamo, da / *We declare under our sole responsibility that*

medicinski pripomoček / *the medical device*	**Charisma Bulk Flow ONE**
Ime, vrsta ali model, številka šarže ali serijska številka, po možnosti izvor in število izdelkov / *Name, type or model, batch or serial number, possibly sources and number of items*	Seznam artiklov je na voljo v Prilogi / *List of Articles see Annex*
Koda EMDN / *EMDN-Code* Koda GMDN / *GMDN code* Koda UMDNS / *UMDNS code* Osnovni UDI-DI / *Basic UDI-DI*	Q 010101 35870 16-724 ++J0141103COMP010103i8C
razreda / *of class*	IIa
v skladu s členom / *according to rule*	8-1, 19-3, v skladu s Prilogo VIII Uredbe o medicinskih pripomočkih 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

izpolnjuje vse določbe Uredbe o medicinskih pripomočkih 2017/745, ki veljajo zanj. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Uveljavljeni usklajeni standardi, nacionalni standardi ali drugi normativni dokumenti / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Drugi uveljavljeni standardi so na voljo v Tehnični dokumentaciji izdelka Charisma Bulk Flow ONE, različica 01 *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Postopek ugotavljanja skladnosti v skladu z / *Conformity assessment procedure acc. to*	Uredbo o medicinskih pripomočkih 2017/745, Priloga IX, poglavje I, oddelka 2 in 3, poglavje III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Priglašeni organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Nemčija CE 0197
Registrska številka / *Registration number*:	HZ 1198082-1
Številka različice / *Version number*	01
Nadomešča Izjavo o skladnosti z dne / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 2022 Kraj, datum / *Place, date*	i.V. Matthias Hartmann zastopnica Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Ime in položaj / *Name and function*

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

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

Medicinski pripomoček / *The medical device*	**Charisma Bulk Flow ONE**
Številka različice / *Version number*	02
Nadomešča Prilogo z dne / *Replaces Annex from*	V01, 08.02.2022
Ta seznam izdelkov velja za naslednjo različico izjave o skladnosti / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Številka artikla / *Article number***	**Ime / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hanau, Nov 22, 2022

Kraj, datum / *Place, date*

i.V. Matthias Hartmann

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

Ime in položaj / *Name and function*

VYHLÁSENIE O ZHODE / *DECLARATION OF CONFORMITY*

Názov a adresa spoločnosti / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Nemecko / *Germany* *SRN: DE-MF-000007705*

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

zdravotnícka pomôcka / *the medical device*	**Charisma Bulk Flow ONE**
Názov, typ alebo model, číslo šarže alebo sériové číslo, prípadne zdroje a počet kusov / *Name, type or model, batch or serial number, possibly sources and number of items*	Zoznam položiek je uvedený v prílohe / *List of Articles see Annex*
Kód EMDN / *EMDN-Code*	Q 010101
Kód GMDN / *GMDN code*	35870
Kód UMDNS / *UMDNS code*	16-724
Základné identifikačné číslo UDI-DI / *Basic UDI-DI*	++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 documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Ďalšie použité normy nájdete v technickej dokumentácii verzie 01 k produktu Charisma Bulk Flow ONE *Further Applied standards see Technical Documentation of Product Charisma Bulk Flow ONE, Version 01*
Postup posúdenia zhody podľa / *Conformity assessment procedure acc. to*	prílohy IX k nariadeniu 2017/745 o zdravotníckych pomôckach, kapitola I, časť 2 a 3 a kapitola III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikovaný orgán / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Nemecko CE 0197
Registračné číslo / *Registration number*:	HZ 1198082-1
Číslo verzie / *Version number*	01
Nahrádza vyhlásenie o zhode z / *Replaces Declaration of Conformity from*	08.02.2022
Hanau, Aug 16, 2022	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Miesto, dátum / *Place, date*	Meno a funkcia / *Name and function*

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

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

Zdravotnícka pomôcka / *The medical device*	**Charisma Bulk Flow ONE**
Číslo verzie / *Version number*	02
Nahrádza prílohu z / *Replaces Annex from*	V01, 08.02.2022
Tento zoznam tovaru je platný pre vyhlásenie o zhode, verzia / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Číslo položky / *Article number***	**Meno / *Name***
+J014660955200	66095520	CHARISMA BULK FLOW SYR 1 x 2G ONE ROW
+J014660953360	66095336	CHARISMA BULK FLOW ONE VALUE-KIT SYRINGE
+J014660947250	66094725	CHARISMA BULK FLOW SYR 1 X 2G ONE

Hanau, Nov 22, 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*

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Umschlag-ID: 5D990E2FCE8F4F86B1E7C2514F716BB1
Status: Abgeschlossen
Betreff: Mit DocuSign abschließen: Charisma Bulk Flow One Annex komplett.pdf
Quellumschlag:
Dokumentenseiten: 16
Signaturen: 16
Umschlagersteller:
Zertifikatsseiten: 4
Initialen: 0
Anette Stadtfeld
Signatur mit Anleitung: Aktiviert
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Hanau, Hessen 63450
Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien
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IP-Adresse: 89.246.249.146

Eintragsverfolgung

Status: Original
22.11.2022 11:09:45
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Unterzeichnerereignisse	Signatur	Zeitstempel
Matthias Hartmann matthias.hartmann@kulzer-dental.com PRRC Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	 Signaturübernahme: Hochgeladenes Signaturbild Mit IP-Adresse: 89.246.249.146	Gesendet: 22.11.2022 11:12:58 Eingesehen: 22.11.2022 11:24:22 Signiert: 22.11.2022 11:24:49

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:
Akzeptiert: 22.11.2022 11:24:22
ID: 102ee691-db8a-44c3-8ed2-40482dadc4f3

Vor-Ort-Unterzeichner – Ereignisse	Signatur	Zeitstempel

Bearbeiterversandereignisse	Status	Zeitstempel

Beauftragtenzustellereignisse	Status	Zeitstempel

Vermittlerversandereignisse	Status	Zeitstempel

Zertifizierter Versand - Ereignisse	Status	Zeitstempel

Kopienereignisse	Status	Zeitstempel

Zeugen-Ereignisse	Signatur	Zeitstempel

Notarereignisse	Signatur	Zeitstempel

Umschlagereignisse – Überblick	Status	Zeitstempel
Umschlag gesendet	Hash-codiert/verschlüsselt	22.11.2022 11:12:58
Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	22.11.2022 11:24:22
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	22.11.2022 11:24:49
Abgeschlossen	Sicherheitsprüfung ausgeführt	22.11.2022 11:24:49

Zahlungen	Status	Zeitstempel

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Dokumentenseiten: 1
Signaturen: 1
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Zertifikatsseiten: 4
Initialen: 0
Leonie Albrecht
Signatur mit Anleitung: Aktiviert
Leipziger Str. 2
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Hanau, Hessen 63450
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Leonie.Albrecht@kulzer-dental.com
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Status: Original
24.11.2022 14:08:41
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Unterzeichnerereignisse	Signatur	Zeitstempel
Matthias Hartmann Matthias.Hartmann@kulzer-dental.com PRRC Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	 Signaturübernahme: Hochgeladenes Signaturbild Mit IP-Adresse: 77.179.101.81	Gesendet: 24.11.2022 14:12:55 Eingesehen: 24.11.2022 15:54:04 Signiert: 24.11.2022 15:54:21

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:
Akzeptiert: 24.11.2022 15:54:04
ID: b65ab8c2-e073-4b07-83cc-3439ae319c4a

Vor-Ort-Unterzeichner – Ereignisse	Signatur	Zeitstempel

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Zeugen-Ereignisse	Signatur	Zeitstempel

Notarereignisse	Signatur	Zeitstempel

Umschlagereignisse – Überblick	Status	Zeitstempel
Umschlag gesendet	Hash-codiert/verschlüsselt	24.11.2022 14:12:55
Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	24.11.2022 15:54:04
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	24.11.2022 15:54:21
Abgeschlossen	Sicherheitsprüfung ausgeführt	24.11.2022 15:54:21

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