

**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 Smart**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*

Q010101

GMDN-Nummer / *GMDN code*

35870

UMDNS-Nummer / *UMDNS code*

16-724

Basis-UDI-DI / *Basic UDI-DI*

++J0141103COMP010103d82

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 1 der Technischen
Dokumentation von Product **Charisma Smart**
*Further Applied standards see Technical Documentation of
Product Charisma Smart, Version 1*Konformitätsbewertungsverfahren nach /
*Conformity assessment procedure acc. to*Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I,
Abschnitt 2 und 3 and Kapitel III*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2
and 3 and Chapter III*Benannte Stelle / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Germany

CE 0197

Registrierungsnr. / *Registration No.:*

HZ 1198082-1

Versionsnummer / *Version number*

1

Ersetzt Konformitätserklärung vom /
Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022

i.V.

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

Versionsnummer Artikelliste/
 Version number article list

01

Ersetzt Artikelliste vom /
 Replaces article list from

N/A

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

UDI-DI / UDI-DI	Artikelnummer / Article number	Name / Name
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Hanau, Nov 29, 2022

i.V.

Dr. Matthias Hartmann

Head of Global Quality, Regulatory & Scientific Services

Kulzer GmbH

Ort, Datum / Place, date

Name und Funktion / Name and function

i.V. Matthias Hartmann

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 Smart

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*

Q010101

Код по GMDN / *GMDN code*

35870

Код по UMDNS / *UMDNS code*

16-724

Основна UDI-DI идентификация / *Basic UDI-DI*

++J0141103COMP010103d82

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 Smart** Версия 1
*Further Applied standards see Technical Documentation of
Product Charisma Smart, Version 1*

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

Регламента за медицинските изделия 2017/745 Приложение
IX, глава I, раздел 2 и 3 и глава III

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

Нотифициран орган / *Notified Body*

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Германия

CE 0197

Регистрационен номер / *Registration number*

HZ 1198082-1

Номер на версия / *Version number*

1

Заменя Декларация за съответствие от /
Replaces Declaration of Conformity from

N/A



Ханау, Nov 29, 2022

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

Място, дата / *Place, date*

Име и длъжност / *Name and function*

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

Списък с артикули / *List of Articles*

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

Медицинското изделие /
The medical device

Charisma Smart

Номер на версия / *Version number*

01

Заменя Приложението от /
Replaces Annex from

N/A

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

01

UDI-DI / <i>UDI-DI</i>	Номер на артикул / <i>Article number</i>	Наименование / <i>Name</i>
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Ханау, Nov 29, 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*

PROHLÁŠENÍ O SHODĚ / DECLARATION OF CONFORMITY

Název a adresa společnosti /
Name and address of the company

Kulzer GmbH
Leipziger Straße 2, 63450 Hanau
Německo / Germany

SRN: DE-MF-000007705

Prohlašujeme na svou výlučnou zodpovědnost, že / We declare under our sole responsibility that
zdravotnický prostředek / *the medical device*

Charisma Smart

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

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

Kód EMDN / *EMDN-Code*

Q010101

Kód GMDN / *GMDN code*

35870

Kód UMDNS / *UMDNS code*

16-724

Základní UDI-DI / *Basic UDI-DI*

++J0141103COMP010103d82

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 Smart**, verze **1**

*Further Applied standards see Technical Documentation of
Product Charisma Smart, Version 1*

Procedura posouzení shody podle /
Conformity assessment procedure acc. to

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

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

Notifikovaná osoba / *Notified Body*

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Německo

CE 0197

Registrační číslo / *Registration number:*

HZ 1198082-1

Číslo verze / *Version number*

1

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

N/A

Hanau, Nov 29, 2022

i.V.

Dr. Matthias Hartmann

Head of Global Quality, Regulatory & Scientific Services

Kulzer GmbH

Místo, datum / *Place, date*

Jméno a funkce / *Name and function*



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



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

Zdravotnický prostředek /
The medical device

Charisma Smart

Číslo verze / *Version number*

01

Nahrazuje přílohu ze dne /
Replaces Annex from

N/A

01

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

UDI-DI / UDI-DI	Číslo zboží / Article number	Název / Name
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G - DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Hanau, Nov 29, 2022

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

Místo, datum / *Place, date*

Jméno a funkce / *Name and function*

**VASTAVUSDEKLARATSIOON / DECLARATION OF CONFORMITY**

Ettevõtte nimi ja aadress /
Name and address of the company

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

Ettevõtte kinnitab oma ainuvastusel, et / We declare under our sole responsibility that
meditsiiniseade / the medical device

Charisma Smart

Nimi, tüüp või mudel, partii või seerianumber,
võimalikud allikad ja osad / Name, type or model,
batch or serial number, possibly sources and
number of items

Artiklite loendit vt lisast / List of Articles see Annex

EMDN-kood / EMDN-Code
GMDN-i kood / GMDN code
UMDNS-i kood / UMDNS code
Põhi-UDI-DI / Basic UDI-DI

Q010101
35870
16-724
++J0141103COMP010103d82

klassil / of class

IIa

kooskõlas reegluga / according to rule

8-1, 19-3 kooskõlas meditsiiniseadme määrusega 2017/745
lisaga VIII / according to Annex VIII of Medical Device Regulation
2017/745

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

Kehtivad harmoniseeritud standardid, riiklikud
standardid ja muud normatiivdokumendid / Applied
harmonised standards, national standards or other
normative documents

EN ISO 4049 - Dentistry- Polymer-based restorative
materials
Muid rakenduvaid standardeid vt tehnilistest
dokumentidest tootele **Charisma Smart**, Version 1
Further Applied standards see Technical Documentation of
Product **Charisma Smart**, Version 1

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

1

Asendab vastavusdeklaratsiooni alates /
Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022

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

Koht, kuupäev / Place, date

Nimi ja funktsioon / Name and function

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



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

Meditsiiniseade /
 The medical device

Charisma Smart

Versiooni number / Version number

01

Asendab lisa alates /
 Replaces Annex from

N/A

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
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Hanau, Nov 29, 2022

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

Koht, kuupäev / Place, date

Nimi ja funktsioon / Name and function

**DECLARACIÓN DE CONFORMIDAD / DECLARATION OF CONFORMITY**Nombre y dirección de la empresa /
*Name and address of the company***Kulzer GmbH**
Leipziger Straße 2, 63450 Hanau
Alemania / Germany
SRN: DE-MF-000007705Declaramos bajo nuestra exclusiva responsabilidad que / *We declare under our sole responsibility that*
el producto sanitario / *the medical device***Charisma Smart**Nombre, tipo o modelo, lote o número de serie,
posiblemente fuentes y número de elementos /
Name, type or model, batch or serial number,
*possibly sources and number of items*Lista de artículos en el Anexo / *List of Articles see Annex*Código EMDN / *EMDN-Code*

Q010101

Código GMDN / *GMDN code*

35870

Código UMDNS / *UMDNS code*

16-724

UDI-DI básico / *Basic UDI-DI*

++J0141103COMP010103d82

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

CE 0197

Número de registro / *Registration number*

HZ 1198082-1

Número de versión / *Version number*

1

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

N/A

Hanau, Nov 29, 2022

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



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

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

UDI-DI / <i>UDI-DI</i>	Número de artículo / <i>Article number</i>	Nombre / <i>Name</i>
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Nov 29, 2022
 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*

**ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ / DECLARATION OF CONFORMITY**Επωνυμία και διεύθυνση εταιρείας /
*Name and address of the company***Kulzer GmbH**
Leipziger Straße 2, 63450 Hanau
Γερμανία / Germany
SRN: DE-MF-000007705**Δηλώνουμε με δική μας ευθύνη ότι / We declare under our sole responsibility that**το ιατροτεχνολογικό προϊόν / *the medical device***Charisma Smart**Επωνυμία, τύπος ή μοντέλο, παρτίδα ή αριθμός
σειράς, πιθανές πηγές και αριθμός ειδών / *Name,
type or model, batch or serial number, possibly
sources and number of items*Κατάλογος ειδών Παράρτημα / *List of Articles see Annex*Κωδικός EMDN / *EMDN-Code*
Κωδικός GMDN / *GMDN code*
Κωδικός UMDNS / *UMDNS code*
Βασικό UDI-DI / *Basic UDI-DI*Q010101
35870
16-724
++J0141103COMP010103d82κλάσης / *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 Smart**, έκδοση 1
*Further Applied standards see Technical Documentation of
Product Charisma Smart, Version 1*Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με
/ *Conformity assessment procedure acc. to*Κανονισμός 2017/745 για τα ιατροτεχνολογικά προϊόντα,
Παράρτημα IX, Κεφάλαιο I, Τμήμα 2 και 3, και Κεφάλαιο III
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section
2 and 3 and Chapter III*Κοινοποιημένος οργανισμός / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Γερμανία

CE 0197

Αριθμός καταχώρησης / *Registration number:*

HZ 1198082-1

Αριθμός έκδοσης / *Version number*

1

Αντικαθιστά τη δήλωση συμμόρφωσης από /
Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022

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

Charisma Smart

Αριθμός έκδοσης / *Version number*

01

Αντικαθιστά το Παράρτημα από /
Replaces Annex from

N/A

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

01

UDI-DI / <i>UDI-DI</i>	Αριθμός είδους / <i>Article number</i>	Όνομα / <i>Name</i>
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Hanau, Nov 29, 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 Smart**Naziv, tip ili model, broj serije, po mogućnosti izvori i broj stavki / *Name, type or model, batch or serial number, possibly sources and number of items*Popis artikala, pogledajte Dodatak / *List of Articles see Annex*šifra EMDN / *EMDN-Code*

Q010101

šifra GMDN / *GMDN code*

35870

šifra UMDNS / *UMDNS code*

16-724

osnovni UDI-DI / *Basic UDI-DI*

++J0141103COMP010103d82

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 Smart**, verzija 1
*Further Applied standards see Technical Documentation of Product Charisma Smart, Version 1*Postupak procjene usklađenosti prema /
Conformity assessment procedure acc. to

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

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

CE 0197

Registracijski broj / *Registration number*

HZ 1198082-1

Broj verzije / *Version number*

1

Zamjenjuje Izjavu o usklađenosti od /
Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022

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

Broj verzije / Version number

01

Zamjenjuje Dodatak od /
 Replaces Annex from

N/A

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
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Hanau, Nov 29, 2022

i.V.

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

Mjesto, datum / Place, date

Ime i funkcija / Name and function

**MEGFELELŐSÉGI NYILATKOZAT / DECLARATION OF CONFORMITY**

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

Kulzer GmbH
Leipziger Straße 2, 63450 Hanau
Németország / Germany

SRN: DE-MF-000007705

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

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

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

EMDN kód / EMDN-Code

Q010101

GMDN kód / GMDN code

35870

UMDNS kód / UMDNS code

16-724

Alapvető UDI-DI / Basic UDI-DI

++J0141103COMP010103d82

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 Smart**, 1. verzió
Further Applied standards see Technical Documentation of
Product **Charisma Smart**, Version 1

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

1

Felváltja a megfelelőségi nyilatkozatot ettől /
Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022

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

Hely, dátum / Place, date

Név és funkció / Name and function

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

Cikkek listája / List of Articles
Melléklet / Annex: Megfelelőségi nyilatkozat / Declaration of Conformity

Az orvostechnikai eszköz /
The medical device

Verziószám / Version number

Felváltja a mellékletet ettől /
Replaces Annex from

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

Charisma Smart

01

N/A

01

UDI-DI / UDI-DI	Cikkszám / Article number	Név / Name
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Nov 29, 2022

Hanau,

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 thatmedicinos prietaisais / *the medical device***Charisma Smart**Pavadinimas, tipas arba modelis, partija arba serijos
numeris, galimi šaltiniai ir elementų skaičius / *Name,
type or model, batch or serial number, possibly
sources and number of items*Prekių sąrašo ieškokite Priede / *List of Articles see Annex*EMDN kodas / *EMDN-Code*

Q010101

GMDN kodas / *GMDN code*

35870

UMDNS kodas / *UMDNS code*

16-724

Pagrindinis UDI-DI / *Basic UDI-DI*

++J0141103COMP010103d82

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 Smart**, techninėje dokumentacijoje, 1 versijoje
*Further Applied standards see Technical Documentation of
Product Charisma Smart, Version 1*]Atitikties patvirtinimo procedūra pagal /
*Conformity assessment procedure acc. to*Medicinos priemonių reglamento 2017/745 IX priedas, I skyrius, 2 ir
3 straipsniai bei III skyrius*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section
2 and 3 and Chapter III*Notifikuotoji įstaiga / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Vokietija

CE 0197

Registracijos numeris / *Registration number*

HZ 1198082-1

Versijos numeris / *Version number*

1

Pakeičia atitikties deklaraciją nuo /
Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbHVieta, data / *Place, date*Vardas, pavardė ir pareigos / *Name and function*Ši atitikties deklaracija galioja 2 metus kartu su atitinkamos pagamintų priemonių partijos pateikimo į rinką dokumentais. / *This
statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced
devices.*



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

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

Versijos numeris / *Version number* 01

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

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
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Hanau, Nov 29, 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 Smart

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*

Q010101

GMDN kods / *GMDN code*

35870

UMDNS kods / *UMDNS code*

16-724

Pamata UDI-DI / *Basic UDI-DI*

++J0141103COMP010103d82

klase / *of class*

Ila

saskaņā ar noteikumu / *according to rule*

8-1, 19-3 saskaņā ar Medicīnisko ierīču regulas 2017/745 VIII pielikumu / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Izmantotie saskaņotie standarti, nacionālie standarti vai citi normatīvie dokumenti / *Applied harmonised standards, national standards or other normative documents*

EN ISO 4049 - Dentistry- Polymer-based restorative materials
Citus izmantotos standartus skatiet tehniskajā dokumentācijā par produktu **Charisma Smart** 1. versija
Further Applied standards see Technical Documentation of Product Charisma Smart, Version 1

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

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

Pilnvarotā iestāde / *Notified Body*

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg/Vācija

CE 0197

Reģistrācijas numurs / *Registration number:*

HZ 1198082-1

Versijas numurs / *Version number*

1

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

N/A

Hānava Nov 29, 2022

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

Vieta, datums / *Place, date*

Vārds, uzvārds un amats / *Name and function*

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



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

Medicīniskā ierīce /
The medical device

Charisma Smart

Versijas numurs / *Version number*

01

Aizstāj pielikumu, kas datēts ar /
Replaces Annex from

N/A

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

01

UDI-DI / <i>UDI-DI</i>		Preces numurs / <i>Article number</i>	Nosaukums / <i>Name</i>
UDI-DI / <i>UDI-DI</i>	Preces numurs / <i>Article number</i>	Nosaukums / <i>Name</i>	
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1	
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2	
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3	
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5	
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1	
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2	
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE	
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G	
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR	
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR	

Hānava Nov 29, 2022


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

Vieta, datums / *Place, date*

Vārds, uzvārds un amats / *Name and function*

**DEKLARACJA ZGODNOŚCI / DECLARATION OF CONFORMITY**

Nazwa i adres firmy /
Name and address of the company

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

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

wyrób medyczny / *the medical device*

Charisma Smart

Nazwa, typ lub model, numer partii lub serii, ewentualnie
źródła i liczba elementów / *Name, type or model, batch
or serial number, possibly sources and number of items*

Wykaz wyrobów znajduje się w załączniku / *List of Articles see
Annex*

Kod wyrobu wg EMDN / *EMDN-Code*
Kod wyrobu wg GMDN / *GMDN code*
Kod wyrobu wg UMDNS / *UMDNS code*
Kod Basic UDI-DI / *Basic UDI-DI*

Q010101
35870
16-724
++J0141103COMP010103d82

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 Smart**, wersja 1
*Further Applied standards see Technical Documentation of
Product Charisma Smart, Version 1*

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

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

Jednostka notyfikowana / *Notified Body*

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg/Niemcy

CE 0197

Numer rejestracyjny / *Registration number*

HZ 1198082-1

Numer wersji / *Version number*

1

Zastępuje Deklarację zgodności z /
Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022


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

Miejscowość, data / *Place, date*

Imię i nazwisko, stanowisko / *Name and function*

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



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

Wyrób medyczny /
 The medical device

Charisma Smart

Numer wersji / Version number

01

Zastępuje załącznik z dnia /
 Replaces Annex from

N/A

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

01

UDI-DI / UDI-DI	Numer wyrobu / Article number	Nazwa / Name
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Hanau, Nov 29, 2022

i.V.

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

Miejscowość, data / Place, date

Imię i nazwisko, stanowisko / Name and function

**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 thatdispozitivul medical / *the medical device***Charisma Smart**Nume, tip sau model, număr de lot sau de serie,
eventual sursele și numărul de articole / *Name,
type or model, batch or serial number, possibly
sources and number of items*Lista de articole, vezi Anexa / *List of Articles see Annex*Cod EMDN / *EMDN-Code*

Q010101

Cod GMDN / *GMDN code*

35870

Cod UMDNS / *UMDNS code*

16-724

UDI-DI de bază / *Basic UDI-DI*

++J0141103COMP010103d82

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
materialsAlte standarde aplicate, vezi documentația tehnică a Produsului
Charisma Smart, Versiunea 1*Further Applied standards see Technical Documentation of
Product Charisma Smart, Version 1*Procedură de evaluare a conformității în conf. cu /
*Conformity assessment procedure acc. to*Regulamentul privind dispozitivele medicale 2017/745, Anexa IX,
Capitolul I, Secțiunile 2 și 3, și Capitolul III*Medical Device Regulation 2017/745 Annex IX, Chapter I,
Section 2 and 3 and Chapter III*Organism notificat / *Notified Body*TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Germany

CE 0197

Numărul de înregistrare / *Registration number*

HZ 1198082-1

Număr versiune / *Version number*

1

Înlocuiește Declarația de conformitate din /
Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022

i.V.

Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbHLoc, dată / *Place, date*Nume și funcție / *Name and function*Prezenta declarație de conformitate este valabilă timp de 2 ani împreună cu documentele de autorizare pentru respectivul lot de
dispozitive produse / *This statement of conformity is valid for 2 years in connection with the release documents for the
respective batch of produced devices.*



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

Dispozitivul medical / **Charisma Smart**
The medical device

Număr versiune / *Version number* 01

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

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

UDI-DI / UDI-DI	Număr articol / Article number	Nume / Name
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Hanau, Nov 29, 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*

**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 SmartIme, 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

Q010101

Koda GMDN / GMDN code

35870

Koda UMDNS / UMDNS code

16-724

Osnovni UDI-DI / Basic UDI-DI

++J0141103COMP010103d82

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 Smart**, različica 1Further Applied standards see Technical Documentation of Product **Charisma Smart**, Version 1Postopek 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

1

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

N/A

Hanau, Nov 29, 2022

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

Kraj, datum / Place, date

Ime in položaj / Name and function

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



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

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

Številka različice / *Version number* 01

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

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

UDI-DI / UDI-DI	Številka artikla / Article number	Ime / Name
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Hanau, Nov 29, 2022

Kraj, datum / *Place, date*


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

Ime in položaj / *Name and function*

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

SRN: DE-MF-000007705

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

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

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

Kód EMDN / EMDN-Code

Q010101

Kód GMDN / GMDN code

35870

Kód UMDNS / UMDNS code

16-724

Základné identifikačné číslo UDI-DI / Basic UDI-DI

++J0141103COMP010103d82

triedy / of class

IIa

podľa pravidiel / according to rule

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

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

Použité harmonizované normy, národné normy
alebo iné normatívne dokumenty / Applied
harmonised standards, national standards or other
normative documentsEN ISO 4049 - Dentistry- Polymer-based restorative
materialsĎalšie použité normy nájdete v technickej dokumentácii verzie 1 k
produktu **Charisma Smart**Further Applied standards see Technical Documentation of
Product **Charisma Smart**, Version 1Postup posúdenia zhody podľa /
Conformity assessment procedure acc. toprílohy IX k nariadeniu 2017/745 o zdravotníckych pomôckach,
kapitola I, časť 2 a 3 a kapitola IIIMedical Device Regulation 2017/745 Annex IX, Chapter I, Section
2 and 3 and Chapter III

Notifikovaný orgán / Notified Body

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg / Nemecko

CE 0197

Registračné číslo / Registration number:

HZ 1198082-1

Číslo verzie / Version number

1

Nahrádza vyhlásenie o zhode z /
Replaces Declaration of Conformity from

N/A

Hanau, Nov 29, 2022

i.V.

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

Miesto, dátum / Place, date

Meno a funkcia / Name and function

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



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

Zdravotnícka pomôcka /
The medical device

Charisma Smart

Číslo verzie / Version number

01

Nahrádza prílohu z /
Replaces Annex from

N/A

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
+J014660603920	66060392	CHARISMA SMART SYR REFILL 1X4G - A1
+J014660603930	66060393	CHARISMA SMART SYR REFILL 1X4G - A2
+J014660603940	66060394	CHARISMA SMART SYR REFILL 1X4G - A3
+J014660603950	66060395	CHARISMA SMART SYR REFILL 1X4G - A3.5
+J014660603960	66060396	CHARISMA SMART SYR REFILL 1X4G - B1
+J014660603970	66060397	CHARISMA SMART SYR REFILL 1X4G - B2
+J014660603980	66060398	CHARISMA SMART SYR REFILL 1X4G – DENTINE
+J014660604410	66060441	CHARISMA SMART SYR ASSORTMENT 6X4G
+J014660960970	66096097	PROC CHARISMA SMART KIT 4X4G SYR
+J014660961020	66096102	PROC CHARISMA SMART KIT 8X4G SYR

Nov 29, 2022
Hanau,

Miesto, dátum / Place, date

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

Meno a funkcia / Name and function

Abschlusszertifikat

Umschlag-ID: E476C9B1DF414580A06A271882A389A5

Status: Abgeschlossen

Betreff: Mit DocuSign abschließen: Charisma Smart combined.pdf

Quellumschlag:

Dokumentenseiten: 28

Signaturen: 28

Umschlagsteller:

Zertifikatsseiten: 4

Initialen: 0

Anette Stadtfeld

Signatur mit Anleitung: Aktiviert

Leipziger Str. 2

Umschlag-ID-Stempel: Aktiviert

Hanau, Hessen 63450

Zeitzone: (UTC+01:00) Amsterdam, Berlin, Bern, Rom, Stockholm, Wien

Anette.Stadtfeld@kulzer-dental.com

IP-Adresse: 89.246.249.146

Eintragsverfolgung

Status: Original

Inhaber: Anette Stadtfeld

Standort: DocuSign

28.11.2022 10:38:07

Anette.Stadtfeld@kulzer-dental.com

Unterzeichnerereignisse**Signatur****Zeitstempel**

Matthias Hartmann

matthias.hartmann@kulzer-dental.com

PRRC

Sicherheitsstufe: E-Mail, Kontoauthentifizierung
(keine)

Gesendet: 28.11.2022 10:42:51

Eingesehen: 29.11.2022 09:19:59

Signiert: 29.11.2022 09:20:34

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

Akzeptiert: 29.11.2022 09:19:59

ID: ed495884-6508-4136-8ff5-7a677332865d

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

28.11.2022 10:42:51

Zertifiziert zugestellt

Sicherheitsprüfung ausgeführt

29.11.2022 09:19:59

Signiervorgang abgeschlossen

Sicherheitsprüfung ausgeführt

29.11.2022 09:20:34

Abgeschlossen

Sicherheitsprüfung ausgeführt

29.11.2022 09:20:34

Zahlungen**Status****Zeitstempel****Vereinbarung bezüglich elektronischer Unterlagen und Signaturen**

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You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

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- ii. send us an email to dieter.lorber@kulzer-dental.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

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