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*	**Venus 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 01010103 Dental composite 35870 Dental composite resin 16-724 Dental filling material, light-curing ++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 1 der Technischen Dokumentation von Product Venus Bulk Flow ONE / *Further Applied standards see Technical Documentation of Product Venus Bulk Flow ONE, Version 1*
Konformitätsbewertungsverfahren nach / *Conformity assessment procedure acc. to*	Medizinprodukte-Verordnung 2017/745 Anhang IX *Medical Device Regulation 2017/745 Annex IX*
Benannte Stelle / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Germany CE 0197
Versionsnummer / *Version number*	01
Ersetzt Konformitätserklärung vom / *Replaces Declaration of Conformity from*	NA
Hanau, 08.02.2022 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.*

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

das Medizinprodukt / *for the medical device*	**Venus Bulk Flow ONE**
Versionsnummer Artikelliste/ *Version number article list*	01
Ersetzt Artikelliste vom / *Replaces article list from*	NA
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***
+J014660947240	66094724	VENUS BULK FLOW PLT 2x10x0,25G ONE
+J014660947230	66094723	VENUS BULK FLOW SYR 1 x 2G ONE
+J014660953350	66095335	VENUS BULK FLOW VALUE-KIT SYRINGE
+J014660953880	66095388	VENUS BULK FLOW ONE VALUE-KIT PLT

Hanau,
08.02.2022

Ort, Datum / *Place, date*

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

Name und Funktion / *Name and function*

OVERENSSTEMMELSESERKLÆRING / *DECLARATION OF CONFORMITY*

Virksomhedens navn og adresse / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, D-63450 Hanau Tyskland / *Germany* *SRN: DE-MF-000007705*

Vi erklærer hermed på eget ansvar, at / *We declare under our sole responsibility that*

det medicinske udstyr / *the medical device*	**Venus Bulk Flow ONE**
Betegnelse, type eller model, batch- eller serienummer samt eventuelt oprindelse og antal emner / *Name, type or model, batch or serial number, possibly sources and number of items*	Produktlisten kan ses i bilaget / *List of Articles see Annex*
EMDN-kode / *EMDN-Code* GMDN-kode / *GMDN code* UMDNS-kode / *UMDNS code* Grundlæggende UDI-DI / *Basic UDI-DI*	Q 01010103 Dental composite 35870 Dental composite resin 16-724 Dental filling material, light-curing ++J0141103COMP010103i8C
i klasse / *of class*	IIa
i henhold til artikel / *according to rule*	8-1, 19-3 i bilag VIII i Europa-Parlamentets og Rådets forordning (EU) 2017/745 om medicinsk udstyr / *according to Annex VIII of Medical Device Regulation 2017/745*

lever op til alle de relevante bestemmelser i forordning (EU) 2017/745 om medicinsk udstyr. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Anvendte harmoniserede standarder, nationale standarder eller andre normative dokumenter / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Andre anvendte standarder kan ses i det tekniske dokumentationsmateriale til produktet Product Venus Bulk Flow ONE, version 1 *Further Applied standards see Technical Documentation of Product Product Venus Bulk Flow ONE, Version 1*
Overensstemmelsesvurderingsprocedure iht. / *Conformity assessment procedure acc. to*	Forordning (EU) 2017/745 om medicinsk udstyr, bilag IX *Medical Device Regulation 2017/745 Annex IX*
Underrettet organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 D-90431 Nürnberg, Tyskland CE 0197
Versionsnummer / *Version number*	01
Erstatter overensstemmelseserklæring fra / *Replaces Declaration of Conformity from*	NA

Hanau,
08.02.2022
Sted, dato / *Place, date*

på vegne af Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH
Navn og stilling / *Name and function*

Denne konformitetserkæring gælder i 2 år i forbindelse med frigivelsesdokumenterne for det aktuelle parti af produceret medicinsk udstyr / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Artikelliste / *List of Articles*
Bilag / *Annex*: Overensstemmelseserklæring / *Declaration of Conformity*

Det medicinske udstyr / *The medical device*	**Venus Bulk Flow ONE**
Versionsnummer / *Version number*	01
Erstatter bilag fra / *Replaces Annex from*	NA
Denne artikelliste er gyldig i forbindelse med overensstemmelseserklæringen version / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Varenummer / *Article number***	**Betegnelse / *Name***
+J014660947240	66094724	VENUS BULK FLOW PLT 2x10x0,25G ONE
+J014660947230	66094723	VENUS BULK FLOW SYR 1 x 2G ONE
+J014660953350	66095335	VENUS BULK FLOW VALUE-KIT SYRINGE
+J014660953880	66095388	VENUS BULK FLOW ONE VALUE-KIT PLT

Hanau, 08.02.2022

Sted, dato / *Place, date*

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

Navn og stilling / *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*	**Venus 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*	Q 01010103 Dental composite 35870 Dental composite resin 16-724 Dental filling material, light-curing
UDI-DI básico / *Basic UDI-DI*	++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 Venus Bulk Flow ONE, versión 1 *Further Applied standards see Technical Documentation of Product Venus Bulk Flow ONE, Version 1*
Procedimiento de evaluación de la conformidad de acuerdo con / *Conformity assessment procedure acc. to*	Reglamento sobre productos sanitarios 2017/745 Anexo IX *Medical Device Regulation 2017/745 Annex IX*
Organismo notificado / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Alemania CE 0197
Número de versión / *Version number*	01
Sustituye a la declaración de conformidad del / *Replaces Declaration of Conformity from*	NA

Hanau,
08.02.2022

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.*

KULZER
MITSUI CHEMICALS GROUP

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

El producto sanitario / *The medical device*	**Venus Bulk Flow ONE**
Número de versión / *Version number*	01
Sustituye al Anexo del / *Replaces Annex from*	NA
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***
+J014660947240	66094724	VENUS BULK FLOW PLT 2x10x0,25G ONE
+J014660947230	66094723	VENUS BULK FLOW SYR 1 x 2G ONE
+J014660953350	66095335	VENUS BULK FLOW VALUE-KIT SYRINGE
+J014660953880	66095388	VENUS BULK FLOW ONE VALUE-KIT PLT

i.V. Matthias Hartmann

Hanau,
08.02.2022

Lugar, fecha / *Place, date*

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

Nombre y cargo / *Name and function*

VAATIMUSTENMUKAISUUSVAKUUTUS / *DECLARATION OF CONFORMITY*

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

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

lääkinnällinen laite / *the medical device*	**Venus Bulk Flow ONE**
Laitteen nimi, tyyppi tai malli, erä- tai sarjanumero, mahdolliset lähteet ja lukumäärä / *Name, type or model, batch or serial number, possibly sources and number of items*	Artikkeliluettelo, ks. liite / *List of Articles see Annex*
EMDN-koodi / *EMDN-Code* GMDN-koodi / *GMDN code* UMDNS-koodi / *UMDNS code* Perus-UDI-DI / *Basic UDI-DI*	Q 01010103 Dental composite 35870 Dental composite resin 16-724 Dental filling material, light-curing ++J0141103COMP010103i8C
luokka / *of class*	IIa
säädös / *according to rule*	8, 19-3] lääkinnällisistä laitteista annetun asetuksen 2017/745 liitteen VIII mukaan / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Soveltuvat harmonisoidut standardit, kansalliset standardit tai muut säädökset / *Applied harmonised standards, national standards or other normative documents*	ISO 4049 - Dentistry– Polymer-based restorative materials Muut sovellettavat standardit, ks. tekniset tiedot Tuotteesta Venus Bulk Flow ONE, versio 1 *Further Applied standards see Technical Documentation of Product Venus Bulk Flow ONE, Version 1*
Vaatimustenmukaisuuden arviointimenettelyn perusta / *Conformity assessment procedure acc. to*	Asetus lääkinnällisistä laitteista 2017/745, liite IX *Medical Device Regulation 2017/745 Annex IX*
Ilmoitettu laitos / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Saksa CE 0197
Versionumero / *Version number*	01
Korvaa vaatimustenmukaisuusvakuutuksen / *Replaces Declaration of Conformity from*	NA
Hanau, 08.02.2022 Paikka, päiväys / *Place, date*	i.V Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nimi ja asema / *Name and function*

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

Artikkeliluettelo / *List of Articles*
Liite / *Annex*: Vaatimustenmukaisuusvakuutus / *Declaration of Conformity*

Lääkinnällinen laite / *The medical device*	**Venus Bulk Flow One**
Versionumero / *Version number*	01
Korvaa liitteen / *Replaces Annex from*	NA
Tämä artikkeliluettelo pätee vaatimustenmukaisuusvakuutuksen versioon / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikkelinumero / *Article number***	**Nimi / *Name***
+J014660947240	66094724	VENUS BULK FLOW PLT 2x10x0,25G ONE
+J014660947230	66094723	VENUS BULK FLOW SYR 1 x 2G ONE
+J014660953350	66095335	VENUS BULK FLOW VALUE-KIT SYRINGE
+J014660953880	66095388	VENUS BULK FLOW ONE VALUE-KIT PLT

Hanau, 08.02.2022

Paikka, päiväys / *Place, date*

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

Nimi ja asema / *Name and function*

DÉCLARATION DE CONFORMITÉ / *DECLARATION OF CONFORMITY*

Nom et adresse de la société / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Allemagne / *Germany* *SRN: DE-MF-000007705*

Nous déclarons sous notre seule responsabilité que / *We declare under our sole responsibility that*

le dispositif médical / *the medical device*	**Venus Bulk Flow ONE**
Nom, type ou modèle, numéro de lot ou de série, éventuellement sources et nombre d'articles / *Name, type or model, batch or serial number, possibly sources and number of items*	Liste des articles voir l'Annexe / *List of Articles see Annex*
Code EMDN / *EMDN-Code* Code GMDN / *GMDN code* code UMDNS / *UMDNS code* UDI-DI de base / *Basic UDI-DI*	Q 01010103 Dental composite 35870 Dental composite resin 16-724 Dental filling material, light-curing ++J0141103COMP010103i8C
de classe / *of class*	IIa
selon la règle / *according to rule*	8-1, 19-3 conformément à l'Annexe VIII du Règlement des Dispositifs Médicaux 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Application de normes harmonisées, de normes nationales ou d'autres documents normatifs / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Autres normes appliquées voir Documentation technique du produit Venus Bulk Flow ONE, version 1 *Further Applied standards see Technical Documentation of Product Venus Bulk Flow ONE, Version 1*
Procédure d'évaluation de la conformité selon / *Conformity assessment procedure acc. to*	l'Annexe IX du Règlement des Dispositifs Médicaux 2017/745 *Medical Device Regulation 2017/745 Annex IX*
Organisme notifié / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Allemagne CE 0197
Numéro de version / *Version number*	01
Remplace la Déclaration de conformité de / *Replaces Declaration of Conformity from*	NA
Hanau, 08.02.2022 Lieu, date / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nom et fonction / *Name and function*

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

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

Le dispositif médical / *The medical device*	**Venus Bulk Flow ONE**
Numéro de version / *Version number*	01
Remplace l'annexe de / *Replaces Annex from*	NA
Cette liste d'articles est valable pour la déclaration de conformité, version / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Numéro de référence / *Article number***	**Nom / *Name***
+J014660947240	66094724	VENUS BULK FLOW PLT 2x10x0,25G ONE
+J014660947230	66094723	VENUS BULK FLOW SYR 1 x 2G ONE
+J014660953350	66095335	VENUS BULK FLOW VALUE-KIT SYRINGE
+J014660953880	66095388	VENUS BULK FLOW ONE VALUE-KIT PLT

Hanau,
08.02.2022

Lieu, date / *Place, date*

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

Nom et fonction / *Name and function*

DICHIARAZIONE DI CONFORMITÀ / *DECLARATION OF CONFORMITY*

Nome e indirizzo della società / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Germania / *Germany* *SRN: DE-MF-000007705*

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

il dispositivo medico / *the medical device*	**Venus Bulk Flow ONE**
Nome, tipo o modello, numero di lotto o di serie, eventualmente fonti e numero di articoli / *Name, type or model, batch or serial number, possibly sources and number of items*	Elenco degli articoli vedi allegato / *List of Articles see Annex*
Codice EMDN / *EMDN-Code* Codice GMDN / *GMDN code* Codice UMDNS / *UMDNS code* UDI-DI di base / *Basic UDI-DI*	Q 01010103 Dental composite 35870 Dental composite resin 16-724 Dental filling material, light-curing ++J0141103COMP010103i8C
di classe / *of class*	IIa
secondo la norma / *according to rule*	8, 19-3 secondo l'allegato VIII del regolamento sui dispositivi medici 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Norme armonizzate applicate, norme nazionali o altri documenti normativi / *Applied harmonised standards, national standards or other normative documents*	ISO 4049 - Dentistry– Polymer-based restorative materials Ulteriori norme applicate vedi Documentazione tecnica di Prodotto Venus Bulk Flow ONE, Versione 1 *Further Applied standards see Technical Documentation of Product Venus Bulk Flow ONE, Version 1*
Procedura di valutazione della conformità secondo il / *Conformity assessment procedure acc. to*	Regolamento sui dispositivi medici 2017/745 Allegato IX *Medical Device Regulation 2017/745 Annex IX*
Organismo notificato / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Norimberga / Germania CE 0197
Numero versione / *Version number*	01
Sostituisce la dichiarazione di conformità di / *Replaces Declaration of Conformity from*	NA
Hanau, 08.02.2022 Luogo, data / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nome e funzione / *Name and function*

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

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

Il dispositivo medico / *The medical device*	**Venus Bulk Flow ONE**
Numero versione / *Version number*	01
Sostituisce l'allegato da / *Replaces Annex from*	NA
Questa lista di articoli è valida per la versione della dichiarazione di conformità / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Numero articolo / *Article number***	**Nome / *Name***
+J014660947240	66094724	VENUS BULK FLOW PLT 2x10x0,25G ONE
+J014660947230	66094723	VENUS BULK FLOW SYR 1 x 2G ONE
+J014660953350	66095335	VENUS BULK FLOW VALUE-KIT SYRINGE
+J014660953880	66095388	VENUS BULK FLOW ONE VALUE-KIT PLT

Hanau, 08.02.2022

Luogo, data / *Place, date*

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

Nome e funzione / *Name and function*

VERKLARING VAN CONFORMITEIT / *DECLARATION OF CONFORMITY*

Naam en adres van de onderneming / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Duitsland / *Germany* *SRN: DE-MF-000007705*

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

het medisch hulpmiddel / *the medical device*	**Venus Bulk Flow ONE**
Naam, type of model, batch of serienummer, mogelijke bronnen en aantal items / *Name, type or model, batch or serial number, possibly sources and number of items*	Voor lijst met artikelen, zie bijlage / *List of Articles see Annex*
EMDN-code / *EMDN-Code* GMDN-code / *GMDN code* UMDNS-code / *UMDNS code* Basis UDI-DI / *Basic UDI-DI*	Q 01010103 Dental composite 35870 Dental composite resin 16-724 Dental filling material, light-curing ++J0141103COMP010103i8C
van klasse / *of class*	IIa
in overeenstemming met regelgeving / *according to rule*	8-1, 19-3 conform Bijlage VIII van de Verordening (EU) 2017/745 betreffende medische hulpmiddelen / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Toegepaste geharmoniseerde normen, nationale normen of andere normatieve documenten / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Voor overige toegepaste normen, zie technische documenten van product Venus Bulk Flow ONE, versie 1 *Further Applied standards see Technical Documentation of Product* Venus Bulk Flow ONE*, Version 1*
Conformiteitsbeoordelingsprocedure in overeenstemming met / *Conformity assessment procedure acc. to*	Verordening (EU) 2017/745 betreffende medische hulpmiddelen Bijlage IX *Medical Device Regulation 2017/745 Annex IX*
Aangemelde instantie / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Duitsland CE 0197
Versienummer / *Version number*	01
Vervangt de verklaring van conformiteit van / *Replaces Declaration of Conformity from*	NA

Hanau,
08.02.2022
Plaats, datum / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH
Naam en functie / *Name and function*

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

Lijst met artikelen / *List of Articles*
Annex / *Annex*: Verklaring van conformiteit / *Declaration of Conformity*

Het medisch hulpmiddel / *The medical device*	**Venus Bulk Flow ONE**
Versienummer / *Version number*	01
Vervangt de bijlage van / *Replaces Annex from*	NA
Deze artikellijst is geldig voor de conformiteitsverklaring, versie / *This article list is valid for the declaration of conformity version*	01

Unieke identificatiecode / *UDI-DI*	**Artikelnummer / *Article number***	**Naam / *Name***
+J014660947240	66094724	VENUS BULK FLOW PLT 2x10x0,25G ONE
+J014660947230	66094723	VENUS BULK FLOW SYR 1 x 2G ONE
+J014660953350	66095335	VENUS BULK FLOW VALUE-KIT SYRINGE
+J014660953880	66095388	VENUS BULK FLOW ONE VALUE-KIT PLT

Hanau, 08.02.2022

Plaats, datum / *Place, date*

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

Naam en functie / *Name and function*

SAMSVARSERKLÆRING / *DECLARATION OF CONFORMITY*

Selskapets navn og adresse / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Tyskland / *Germany* *SRN: DE-MF-000007705*

Vi erklærer på eget ansvar at / *We declare under our sole responsibility that*

det medisinske utstyret / *the medical device*	**Venus Bulk Flow ONE**
Navn, type eller modell, parti- eller serienummer, eventuelt kilder og antall elementer / *Name, type or model, batch or serial number, possibly sources and number of items*	Liste over artikler, se vedlegg / *List of Articles, see Annex*
EMDN-kode / *EMDN-Code* GMDN-kode / *GMDN code* UMDNS-kode / *UMDNS code* Grunnleggende UDI-DI / *Basic UDI-DI*	Q 01010103 Dental composite 35870 Dental composite resin 16-724 Dental filling material, light-curing ++J0141103COMP010103i8C
i klasse / *of class*	IIa
i henhold til regel / *according to rule*	8-1, 19-3 i henhold til vedlegg VIII i forordning 2017/745 om medisinsk utstyr / *according to Annex VIII of Medical Device Regulation 2017/745*

oppfyller alle relevante bestemmelser i forordning 2017/745 om medisinsk utstyr. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Anvendte harmoniserte standarder, nasjonale standarder eller andre normative dokumenter / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4049 - Dentistry– Polymer-based restorative materials Ytterligere anvendte standarder, se teknisk dokumentasjon for produktet Venus Bulk Flow ONE, versjon 1 *Further Applied standards see Technical Documentation of Product Venus Bulk Flow ONE, Version 1*
Prosedyre for samsvarsvurdering i henhold til / *Conformity assessment procedure acc. to*	forordning 2017/745 om medisinsk utstyr vedlegg IX *Medical Device Regulation 2017/745 Annex IX*
Teknisk kontrollorgan / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Tyskland CE 0197
Versjonsnummer / *Version number*	01
Erstatter samsvarserklæring fra / *Replaces Declaration of Conformity from*	NA

Hanau,
08.02.2022
Sted, dato / *Place, date*

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

KULZER
MITSUI CHEMICALS GROUP

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

Det medisinske utstyret / *The medical device*	**Venus Bulk Flow ONE**
Versjonsnummer / *Version number*	01
Erstatter vedlegg fra / *Replaces Annex from*	NA
Denne artikkellisten gjelder for samsvarserklæringsversjon / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikkelnummer / *Article number***	**Navn / *Name***
+J014660947240	66094724	VENUS BULK FLOW PLT 2x10x0,25G ONE
+J014660947230	66094723	VENUS BULK FLOW SYR 1 x 2G ONE
+J014660953350	66095335	VENUS BULK FLOW VALUE-KIT SYRINGE
+J014660953880	66095388	VENUS BULK FLOW ONE VALUE-KIT PLT

i.V.

Hanau, 08.02.2022

Sted, dato / *Place, date*

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

Navn og funksjon / *Name and function*

FÖRSÄKRAN OM ÖVERENSSTÄMMELSE / *DECLARATION OF CONFORMITY*

Företagets namn och adress / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Tyskland / *Germany* *SRN: DE-MF-000007705*

Vi försäkrar på eget ansvar att / *We declare under our sole responsibility that*

den medicintekniska produkten / *the medical device*	**Venus Bulk Flow ONE**
Namn, typ eller modell, batch eller serienummer, eventuella källor och antal artiklar / *Name, type or model, batch or serial number, possibly sources and number of items*	Se bilaga för lista över artiklar / *List of Articles see Annex*
EMDN-kod / *EMDN-Code* GMDN-kod / *GMDN code* UMDNS-kod / *UMDNS code* Grundläggande UDI-DI / *Basic UDI-DI*	Q 01010103 Dental composite 35870 Dental composite resin 16-724 Dental filling material, light-curing ++J0141103COMP010103i8C
i klass / *of class*	IIa
enligt paragraf / *according to rule*	8, 19-3 enligt bilaga VIII i förordningen om medicintekniska produkter 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

uppfyller kraven i förordningen om medicintekniska produkter 2017/745 som gäller produkten. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Tillämpade harmoniserade standarder, nationella standarder eller andra normerande dokument / *Applied harmonised standards, national standards or other normative documents*	ISO 4049 - Dentistry– Polymer-based restorative materials För ytterligare tillämpade standarder, se teknisk dokumentation för produkten Venus Bulk Flow ONE, version 1 *Further Applied standards see Technical Documentation of Product Venus Bulk Flow ONE, Version 1*
Förfarande för bedömning av överensstämmelse enl. / *Conformity assessment procedure acc. to*	förordning om medicintekniska 2017/745 bilaga IX *Medical Device Regulation 2017/745 Annex IX*
Anmält organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Tyskland CE 0197
Versionsnummer / *Version number*	01
Ersätter försäkran om överensstämmelse från / *Replaces Declaration of Conformity from*	NA

Hanau, 08.02.2022

Ort, datum / *Place, date*

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

Namn och funktion / *Name and function*

Denna försäkran om överensstämmelse är giltig i 2 år tillsammans med dokumenten för frisläppande av respektive tillverkningsserie av medicintekniska produkter / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices*

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

Den medicintekniska produkten / *The medical device*	**Venus Bulk Flow ONE**
Versionsnummer / *Version number*	01
Ersätter bilaga från / *Replaces Annex from*	NA
Denna artikellista gäller för förklaring av överensstämmelse version / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Namn / *Name***
+J014660947240	66094724	VENUS BULK FLOW PLT 2x10x0,25G ONE
+J014660947230	66094723	VENUS BULK FLOW SYR 1 x 2G ONE
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Hanau, 08.02.2022

Ort, datum / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
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Namn och funktion / *Name and function*