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*	**Signum liquid**
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*	Q010699 38781 16-723
Basis-UDI-DI / *Basic UDI-DI*	++J0141103CBVM0205e9Q
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*	Weitere angewandte Normen siehe Version 1 der Technischen Dokumentation von Signum liquid / *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
Konformitätsbewertungsverfahren nach / *Conformity assessment procedure acc. to*	Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I, Abschnitt 2 und 3 und 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*	N/A
Hanau, Dez 12, 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.*

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*	**Signum liquid**
Наименование, тип или модел, партиден или сериен номер, евентуално произход и брой елементи / *Name, type or model, batch or serial number, possibly sources and number of items*	Списък с артикули, вижте Приложението / *List of Articles see Annex*
Код по EMDN / *EMDN-Code* Код по GMDN / *GMDN code* Код по UMDNS / *UMDNS code* Основна UDI-DI идентификация / *Basic UDI-DI*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Други приложени стандарти, вижте техническата документация на продукт Signum liquid Версия 1 *Further Applied standards see Technical Documentation of Product Signum liquid, 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*	01
Заменя Декларация за съответствие от / *Replaces Declaration of Conformity from*	N/A
Ханау, Dez 12, 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*

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.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Další použité normy najdete v technické dokumentaci k výrobku Signum liquid, verze 1 *Further Applied standards see Technical Documentation of Product* Signum liquid*, 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*	01
Nahrazuje Prohlášení o shodě ze dne / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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*.

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Andre anvendte standarder kan ses i det tekniske dokumentationsmateriale til produktet Signum liquid, version 1 *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
Overensstemmelsesvurderingsprocedure iht. / *Conformity assessment procedure acc. to*	Forordning (EU) 2017/745 om medicinsk udstyr, bilag IX, kapitel I, afsnit 2 og 3 samt kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Underrettet organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 D-90431 Nürnberg, Tyskland CE 0197
Registreringsnummer / *Registration number*:	HZ 1198082-1
Versionsnummer / *Version number*	01
Erstatter overensstemmelseserklæring fra / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Para otras normas aplicadas consulte la documentación técnica del producto Signum liquid, versión 1 *Further Applied standards see Technical Documentation of Product* Signum liquid*, 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*	01
Sustituye a la declaración de conformidad del / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Autres normes appliquées voir Documentation technique du produit Signum liquid, version 1 *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
Procédure d'évaluation de la conformité selon / *Conformity assessment procedure acc. to*	Règlement relatif aux dispositifs médicaux 2017/745 Annexe IX, Chapitre I, Paragraphes 2 et 3 et Chapitre III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organisme notifié / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Allemagne CE 0197
Numéro d'enregistrement / *Registration number*:	HZ 1198082-1
Numéro de version / *Version number*	01
Remplace la Déclaration de conformité de / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική τεκμηρίωση του προϊόντος Signum liquid, έκδοση 1 *Further Applied standards see Technical Documentation of Product Signum liquid, 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*	01
Αντικαθιστά τη δήλωση συμμόρφωσης από / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod Signum liquid, verzija 1 *Further Applied standards see Technical Documentation of Product Signum liquid, 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*	01
Zamjenjuje Izjavu o usklađenosti od / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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*

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.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	További alkalmazott szabványokat lásd a műszaki dokumentációban, termék: Signum liquid, 1. verzió *Further Applied standards see Technical Documentation of Product Signum liquid, 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*	01
Felváltja a megfelelőségi nyilatkozatot ettől / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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*

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.

DEARBHÚ COMHRÉIREACHTA / *DECLARATION OF CONFORMITY*

Ainm agus seoladh na cuideachta / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau An Ghearmáin / *Germany* *SRN: DE-MF-000007705*

Dearbhaíonn muid faoinár gcúram aonair go bhfuil / *We declare under our sole responsibility that*

an fheiste leighis / *the medical device*	**Signum liquid**
Ainm, cineál nó leagan, baisc nó sraithuimhir, b'fhéidir foinsí agus líon earraí / *Name, type or model, batch or serial number, possibly sources and number of items*	Féach Aguisín do Liosta Airteagal /*List of Articles see Annex*
Cód-EMDN / *EMDN-Code* cód GMDN / *GMDN code* cód UMDNS / *UMDNS code* UDI-DI Bunúsach / *Basic UDI-DI*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
d'aicme / *of class*	IIa
de réir rialach / *according to rule*	8-1, 19-3 de réir Aguisín VIII de Rialachán Feiste Leighis 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

comhlíonann sé na forálacha uilig sa Rialachán Feiste Leighis 2017/745 atá i bhfeidhm air. /
meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.

Caighdeáin chomhoiriúnaithe i bhfeidhm, caighdeáin náisiúnta nó cáipéisí normatacha eile / *Applied harmonised standards, national standards or other normative documents*	Féach Cáipéisíocht Theicniúil do Chaighdeáin Bhreise i bhfeidhm ar Táirge Signum liquid,, Leagan 1 / *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
Gnáthamh measúnaithe comhréireachta de réir / *Conformity assessment procedure acc. to*	Rialachán Feiste Leighis 2017/745 Iarscríbhinn IX, Caibidil I, Alt 2 agus 3 agus Caibidil III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Comhlacht a dtugtar fógra dó / *Notified Body*	TÜV Rheinland LGA Táirgí GmbH Tillystrasse 2 90431 Nürnberg / An Ghearmáin CE 0197
Uimhir chláraithe / *Registration number*:	HZ 1198082-1
Uimhir leagain / *Version number*	01
Tagann sé in áit Dearbhú Comhréireachta ó / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 2022 Láthair, dáta / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Ainm agus feidhm / *Name and function*

Tá an dearbhú comhréireachta seo bailí feadh 2 bhliain i dtaca leis na cáipéisí fuascailte don bhaisc faoi seach de na feistí táirgthe / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
di classe / *of class*	IIa
secondo la norma / *according to rule*	8-1, 19-3 secondo l'allegato VIII del regolamento sui dispositivi medici 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Norme armonizzate applicate, norme nazionali o altri documenti normativi / *Applied harmonised standards, national standards or other normative documents*	Ulteriori norme applicate vedi Documentazione tecnica di Prodotto Signum liquid, Versione 1 *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
Procedura di valutazione della conformità secondo il / *Conformity assessment procedure acc. to*	Regolamento sui dispositivi medici 2017/745 Allegato IX, Capitolo I, Paragrafi 2 e 3, e Capitolo III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organismo notificato / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Norimberga / Germania CE 0197
Numero di registrazione / *Registration number*:	HZ 1198082-1
Numero versione / *Version number*	01
Sostituisce la dichiarazione di conformità di / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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.

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	atkuriamosiomis medžiagomis Kitus taikomus standartus žr. produkto Signum liquid, techninėje dokumentacijoje, 1 versijoje *Further Applied standards see Technical Documentation of Product Signum liquid, 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*	01
Pakeičia atitikties deklaraciją nuo / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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*

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.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Voor overige toegepaste normen, zie technische documenten van product Signum liquid, versie 1 *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
Conformiteitsbeoordelingsprocedure in overeenstemming met / *Conformity assessment procedure acc. to*	Verordening (EU) 2017/745 betreffende medische hulpmiddelen bijlage IX, hoofdstuk I, sectie 2 en 3 en hoofdstuk III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Aangemelde instantie / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Duitsland CE 0197
Registratienummer / *Registration number*:	HZ 1198082-1
Versienummer / *Version number*	01
Vervangt de verklaring van conformiteit van / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Pozostałe stosowane normy znajdują się w dokumentacji technicznej produktu Signum liquid, wersja 1 *Further Applied standards see Technical Documentation of Product Signum liquid, 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*	01
Zastępuje Deklarację zgodności z / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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*

DECLARAÇÃO DE CONFORMIDADE / *DECLARATION OF CONFORMITY*

Nome e morada da empresa / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Alemanha / *Germany* *SRN: DE-MF-000007705*

Declaramos, sob nossa exclusiva responsabilidade, que / *We declare under our sole responsibility that*

o dispositivo médico / *the medical device*	**Signum liquid**
Nome, tipo ou modelo, número de lote ou de série, possivelmente origem e quantidade de itens / *Name, type or model, batch or serial number, possibly sources and number of items*	Lista de artigos, ver Anexo / *List of Articles see Annex*
Código EMDN / *EMDN-Code* Código GMDN / *GMDN code* Código UMDNS / *UMDNS code* UDI-DI básico / *Basic UDI-DI*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
da classe / *of class*	IIa
em conformidade com o regulamento / *according to rule*	8-1, 19-3 em conformidade com o Anexo VIII do Regulamento 2017/745 relativo aos Dispositivos Médicos / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Normas harmonizadas aplicadas, normas nacionais ou outros documentos normativos / *Applied harmonised standards, national standards or other normative documents*	Outras normas aplicadas, ver Documentação técnica do produto Signum liquid, Versão 1 *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
Procedimento de avaliação da conformidade de acordo com / *Conformity assessment procedure acc. to*	Anexo IX do Regulamento 2017/745 relativo aos Dispositivos Médicos, Capítulo I, secção 2 e 3 e Capítulo III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organismo notificado / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Alemanha CE 0197
Número de registo / *Registration number*:	HZ 1198082-1
Número de versão / *Version number*	01
Substitui a Declaração de Conformidade de / *Replaces Declaration of Conformity from*	N/A

Hanau, Dez 12, 2022

Local, data / *Place, date*

p.p. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH
Nome e função / *Name and function*

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

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Alte standarde aplicate, vezi documentația tehnică a Produsului Signum liquid, Versiunea 1 *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
Procedură de evaluare a conformității în conf. cu / *Conformity assessment procedure acc. to*	Regulamentul privind dispozitivele medicale 2017/745, Anexa IX, Capitolul I, Secțiunile 2 și 3, și Capitolul III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organism notificat / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Germania CE 0197
Numărul de înregistrare / *Registration number*:	HZ 1198082-1
Număr versiune / *Version number*	01
Înlocuiește Declarația de conformitate din / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
i klass / *of class*	IIa
enligt paragraf / *according to rule*	8-1, 19-3 enligt bilaga VIII i förordningen om medicintekniska produkter 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Tillämpade harmoniserade standarder, nationella standarder eller andra normerande dokument / *Applied harmonised standards, national standards or other normative documents*	För ytterligare tillämpade standarder, se teknisk dokumentation för produkten Signum liquid, version 1 *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
Förfarande för bedömning av överensstämmelse enl. / *Conformity assessment procedure acc. to*	förordning om medicintekniska 2017/745 bilaga IX, kapitel I, avsnitt 2 och 3 och kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Anmält organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Tyskland CE 0197
Registreringsnummer / *Registration number*:	HZ 1198082-1
Versionsnummer / *Version number*	01
Ersätter försäkran om överensstämmelse från / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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.*

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*	**Signum liquid**
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*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Drugi uveljavljeni standardi so na voljo v Tehnični dokumentaciji izdelka Signum liquid, različica 1 *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
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*	N/A
Hanau, Dez 12, 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.*

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*	**Signum liquid**
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* Kód GMDN / *GMDN code* Kód UMDNS / *UMDNS code* Základné identifikačné číslo UDI-DI / *Basic UDI-DI*	Q010699 38781 16-723 ++J0141103CBVM0205e9Q
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*	Ďalšie použité normy nájdete v technickej dokumentácii verzie 1 k produktu Signum liquid *Further Applied standards see Technical Documentation of Product Signum liquid, Version 1*
Postup posúdenia zhody podľa / *Conformity assessment procedure acc. to*	prílohy IX k nariadeniu 2017/745 o zdravotníckych pomôckach, kapitola I, časť 2 a 3 a kapitola III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikovaný orgán / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Nemecko CE 0197
Registračné číslo / *Registration number*:	HZ 1198082-1
Číslo verzie / *Version number*	01
Nahrádza vyhlásenie o zhode z / *Replaces Declaration of Conformity from*	N/A
Hanau, Dez 12, 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*

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.

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

das Medizinprodukt / *for the medical device*	Signum liquid
Versionsnummer Artikelliste/ *Version number article list*	01
Ersetzt Artikelliste vom / *Replaces article list from*	N/A
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

Il dispositivo medico / *The medical device*	Signum liquid
Numero versione / *Version number*	01
Sostituisce l'allegato da / *Replaces Annex from*	N/A
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

Медицинското изделие / *The medical device*	Signum liquid
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 / *UDI-DI*	**Номер на артикул / *Article number***	**Наименование / *Name***
+J014647141980	64714198	Signum liquid, 4 ml

Ханау, Dez 12, 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*

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

Zdravotnický prostředek / *The medical device*	Signum liquid
Číslo verze / *Version number*	01
Nahrazuje přílohu ze dne / *Replaces Annex from*	N/A
Tento seznam zboží platí pro verzi prohlášení o shodě / *This article list is valid for the declaration of conformity version:*	01

UDI-DI / *UDI-DI*	**Číslo zboží / *Article number***	**Název / *Name***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

Det medicinske udstyr / *The medical device*	Signum liquid
Versionsnummer / *Version number*	01
Erstatter bilag fra / *Replaces Annex from*	N/A
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

El producto sanitario / *The medical device*	Signum liquid
Número de versión / *Version number*	01
Sustituye al Anexo del / *Replaces Annex from*	N/A
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

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

UDI-DI / *UDI-DI*	**Numéro de référence / *Article number***	**Nom / *Name***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

Το ιατροτεχνολογικό προϊόν / *The medical device*	Signum liquid
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 / *UDI-DI*	**Αριθμός είδους / *Article number***	**Όνομα / *Name***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

Medicinski proizvod / *The medical device*	Signum liquid
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

Az orvostechnikai eszköz / *The medical device*	Signum liquid
Verziószám / *Version number*	01
Felváltja a mellékletet ettől / *Replaces Annex from*	N/A
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***
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Hanau, Dez 12, 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*

Liosta Airteagal / *List of Articles*
Aguisín / *Annex*: Dearbhú Comhréireachta / *Declaration of Conformity*

An fheiste leighis / *The medical device*	Signum liquid
Uimhir leagain / *Version number*	01
Tagann sé in áit Aguisín ó / *Replaces Annex from*	N/A
Tá an liosta airteagail bailí don dearbhú comhréireachta leagan / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Uimhir airteagail / *Article number***	**Ainm / *Name***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 2022

Láthair, dáta / *Place, date*

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

Ainm agus feidhm / *Name and function*

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

Medicinos prietaisas / *The medical device*	Signum liquid
Versijos numeris / *Version number*	01
Pakeičia Priedą nuo / *Replaces Annex from*	N/A
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

Het medisch hulpmiddel / *The medical device*	Signum liquid
Versienummer / *Version number*	01
Vervangt de bijlage van / *Replaces Annex from*	N/A
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

Wyrób medyczny / *The medical device*	Signum liquid
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

O dispositivo médico / *The medical device*	Signum liquid
Número de versão / *Version number*	01
Substitui o Anexo de / *Replaces Annex from*	N/A
A presente lista de artigos é válida para a versão da declaração de conformidade / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Número de artigo / *Article number***	**Nome / *Name***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 2022

Local, data / *Place, date*

i.V. Matthias Hartmann

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

Nome e função / *Name and function*

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

Dispozitivul medical / *The medical device*	Signum liquid
Număr versiune / *Version number*	01
Înlocuiește Anexa de la / *Replaces Annex from*	N/A
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

Den medicintekniska produkten / *The medical device*	Signum liquid
Versionsnummer / *Version number*	01
Ersätter bilaga från / *Replaces Annex from*	N/A
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***
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Hanau, Dez 12, 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*

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

Medicinski pripomoček / *The medical device*	Signum liquid
Številka različice / *Version number*	01
Nadomešča Prilogo z dne / *Replaces Annex from*	N/A
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*

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

Zdravotnícka pomôcka / *The medical device*	Signum liquid
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***
+J014647141980	64714198	Signum liquid, 4 ml

Hanau, Dez 12, 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*