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*	**Retraxil**
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*	Q010204
GMDN-Nummer / *GMDN code*	46423
UMDNS-Nummer / *UMDNS code*	-
Basis-UDI-DI / *Basic UDI-DI*	++J0141209REP0204a3E
der Klasse / *of class*	I
nach Regel / *according to rule*	5 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 01 der Technischen Dokumentation von Product Retraxil/ *Further Applied standards see Technical Documentation of Product Retraxil, Version 01*
Konformitätsbewertungsverfahren nach / *Conformity assessment procedure acc. to*	Medizinprodukte-Verordnung 2017/745 Art 52 (7) *Medical Device Regulation 2017/745 Art 52 (7)*
Benannte Stelle / *Notified Body*	-
Registrierungsnr. / *Registration No.*:	-
Versionsnummer / *Version number*	01
Ersetzt Konformitätserklärung vom / *Replaces Declaration of Conformity from*	-

Hanau, 07.08.2024

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

Ort, Datum / *Place, date*

Name und Funktion / *Name and function*

Diese Konformitätserklärung ist gültig für 2 Jahre in Verbindung mit den Freigabe-Dokumenten für die jeweilige Charge der produzierten Medizinprodukte / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

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

das Medizinprodukt / *for the medical device*	**Retraxil**
Versionsnummer Artikelliste / *Version number article list*	01
Ersetzt Artikelliste vom / *Replaces article list from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

Ort, Datum / *Place, date*

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

Name und Funktion / *Name and function*

ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ / *DECLARATION OF CONFORMITY*

Име и адрес на фирмата / *Name and address of the company*	*Kulzer GmbH* *Leipziger Straße 2, 63450 Hanau* *Германия / Germany* *SRN: DE-MF-000007705*

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

медицинското изделие / *the medical device*	**Retraxil**
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*	Q010204
Код по GMDN / *GMDN code*	46423
Код по UMDNS / *UMDNS code*	-
Основна UDI-DI идентификация / *Basic UDI-DI*	++J0141209REP0204a3E
от клас / *of class*	I
съгласно правило / *according to rule*	5 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 Retraxil Версия 01 *Further Applied standards see Technical Documentation of Product Retraxil, Version 01*
Процедура за оценка на съответствието съгласно / *Conformity assessment procedure acc. to*	Регламента за медицинските изделия 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Нотифициран орган / *Notified Body*	-
Регистрационен номер / *Registration number*:	-
Номер на версия / *Version number*	01
Заменя Декларация за съответствие от / *Replaces Declaration of Conformity from*	-
Ханау, 28.01.2025 Място, дата / *Place, date*	i.V. от името на д-р Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Име и длъжност / *Name and function*

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

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

Медицинското изделие / *The medical device*	**Retraxil**
Номер на версия / *Version number*	01
Заменя Приложението от / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETRAXIL SAMPLE 1X1G

Ханау, 28.01.2025

Място, дата / *Place, date*

i.V.

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

Име и длъжност / Name and function

PROHLÁŠENÍ O SHODĚ / *DECLARATION OF CONFORMITY*

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

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

zdravotnický prostředek / *the medical device*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
třídy / *of class*	I
podle pravidla / *according to rule*	5 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 Retraxil, verze 01 *Further Applied standards see Technical Documentation of Product Retraxil, Version* 01
Procedura posouzení shody podle / *Conformity assessment procedure acc. to*	nařízení 2017/745 o zdravotnických prostředcích, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Notifikovaná osoba / *Notified Body*	-
Registrační číslo / *Registration number*:	-
Číslo verze / *Version number*	01
Nahrazuje Prohlášení o shodě ze dne / *Replaces Declaration of Conformity from*	-
Hanau, 28.01.2025 Místo, datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** 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*.

KULZER
MITSUI CHEMICALS GROUP

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

Zdravotnický prostředek / *The medical device*	**Retraxil**
Číslo verze / *Version number*	01
Nahrazuje přílohu ze dne / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETRAXIL SAMPLE 1X1G

Hanau, 28.01.2025

Místo, datum / *Place, date*

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

Jméno a funkce / *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*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
i klasse / *of class*	I
i henhold til artikel / *according to rule*	5 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 , Retraxil version [01 *Further Applied standards see Technical Documentation of Product Retraxil, Version 01*
Overensstemmelsesvurderingsprocedure iht. / *Conformity assessment procedure acc. to*	Forordning (EU) 2017/745 om medicinsk udstyr, Art 52 (7) *Medical Device Regulation 2017/745 Art 52 (7)*
Underrettet organ / *Notified Body*	-
Registreringsnummer / *Registration number*:	-
Versionsnummer / *Version number*	01
Erstatter overensstemmelseserklæring fra / *Replaces Declaration of Conformity from*	-
Hanau, 07.08.2024 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*	**Retraxil**
Versionsnummer / *Version numbe r*	01
Erstatter bilag fra / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

Sted, dato / *Place, date*

i.V.

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*	**Retraxil**
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*	Q010204 46423 - ++ J0141209REP0204a3E
de la clase / *of class*	I
de acuerdo con la norma / *according to rule*	5 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 Retraxil, versión 01 *Further Applied standards see Technical Documentation of Product Retraxil Version* [01
Procedimiento de evaluación de la conformidad de acuerdo con / *Conformity assessment procedure acc. to*	Reglamento sobre productos sanitarios 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Organismo notificado / *Notified Body*	-
Número de registro / *Registration number*:	-
Número de versión / *Version number*	01
Sustituye a la declaración de conformidad del / *Replaces Declaration of Conformity from*	-

Hanau, 07.08.2024

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

Lugar, fecha / *Place, date*

Nombre y cargo / *Name and function*

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

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

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

UDI-DI / *UDI-DI*	**Número de artículo / *Article number***	**Nombre / *Name***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

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*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
luokka / *of class*	I
säädös / *according to rule*	5 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*	- Muut sovellettavat standardit, ks. tekniset tiedot tuotteesta Retraxil , versio [01 *Further Applied standards see Technical Documentation of Product Retraxil , Version* 01
Vaatimustenmukaisuuden arviointimenettelyn perusta / *Conformity assessment procedure acc. to*	Asetus lääkinnällisistä laitteista 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Ilmoitettu laitos / *Notified Body*	-
Rekisteröintinumero / *Registration number*:	-
Versionumero / *Version number*	01
Korvaa vaatimustenmukaisuusvakuutuksen / *Replaces Declaration of Conformity from*	-
Hanau, 07.08.2024 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*	**Retraxil**
Versionumero / *Version number*	01
Korvaa liitteen / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

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*	**Retraxil**
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*	Q010204
Code GMDN / *GMDN code*	46423
code UMDNS / *UMDNS code*	-
UDI-DI de base / *Basic UDI-DI*	++ J0141209REP0204a3E
de classe / *of class*	I
selon la règle / *according to rule*	5 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 Retraxil, version [01 *Further Applied standards see Technical Documentation of Product Retraxil, Version* [01
Procédure d'évaluation de la conformité selon / *Conformity assessment procedure acc. to*	Règlement relatif aux dispositifs médicaux 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Organisme notifié / *Notified Body*	-
Numéro d'enregistrement / *Registration number*:	-
Numéro de version / *Version number*	01
Remplace la Déclaration de conformité de / *Replaces Declaration of Conformity from*	-
Hanau, 07.08.2024 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*	**Retraxil**
Numéro de version / *Version number*	01
Remplace l'annexe de / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

Lieu, date / *Place, date*

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

Nom et fonction / *Name and function*

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ / *DECLARATION OF CONFORMITY*

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

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

το ιατροτεχνολογικό προϊόν / *the medical device*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
κλάσης / *of class*	I
σύμφωνα με τον κανόνα / *according to rule*	5 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 Retraxil, έκδοση 01 *Further Applied standards see Technical Documentation of Product Retraxil, Version 01*
Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με / *Conformity assessment procedure acc. to*	Κανονισμός 2017/745 για τα ιατροτεχνολογικά προϊόντα, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Κοινοποιημένος οργανισμός / *Notified Body*	-
Αριθμός καταχώρησης / *Registration number*:	-
Αριθμός έκδοσης / *Version number*	01
Αντικαθιστά τη δήλωση συμμόρφωσης από / *Replaces Declaration of Conformity from*	-
Hanau, 28.01.2025 Τόπος, ημερομηνία / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Ονοματεπώνυμο και τίτλος / *Name and function*

Αυτή η δήλωση συμμόρφωσης ισχύει για 2 χρόνια σε σχέση με τα έγγραφα κυκλοφορίας για την αντίστοιχη παρτίδα των παραγόμενων προϊόντων. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

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

Το ιατροτεχνολογικό προϊόν / *The medical device*	**Retraxil**
Αριθμός έκδοσης / *Version number*	01
Αντικαθιστά το Παράρτημα από / *Replaces Annex from*	-
Αυτός ο κατάλογος προϊόντων ισχύει για την έκδοση δήλωσης συμμόρφωσης / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Αριθμός είδους / *Article number***	**Όνομα / *Name***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETRAXIL SAMPLE 1X1G

Hanau, 28.01.2025

Τόπος, ημερομηνία / *Place, date*

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

Ονοματεπώνυμο και τίτλος / *Name and function*

IZJAVA O USKLAĐENOSTI / *DECLARATION OF CONFORMITY*

Naziv i adresa tvrtke / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Njemačka / *Germany* *SRN: DE-MF-000007705*

Izjavljujemo pod punom odgovornošću da / *We declare under our sole responsibility that*

medicinski proizvod / *the medical device*	**Retraxil**
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*	Q010204
šifra GMDN / *GMDN code*	46423
šifra UMDNS / *UMDNS code*	-
osnovni UDI-DI / *Basic UDI-DI*	++J0141209REP0204a3E
klase / *of class*	I
u skladu s pravilom / *according to rule*	5 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 Retraxil, verzija 01 *Further Applied standards see Technical Documentation of Product Retraxil, Version* 01
Postupak procjene usklađenosti prema / *Conformity assessment procedure acc. to*	Uredbi 2017/745 o medicinskim proizvodima, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Obaviješteno tijelo / *Notified Body*	-
Registracijski broj / *Registration number*:	-
Broj verzije / *Version number*	01
Zamjenjuje Izjavu o usklađenosti od / *Replaces Declaration of Conformity from*	-
Hanau, 28.01.2025	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Mjesto, datum / *Place, date*	Ime i funkcija / *Name and function*

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

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

Medicinski proizvod / *The medical device*	**Retraxil**
Broj verzije / *Version number*	01
Zamjenjuje Dodatak od / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETRAXIL SAMPLE 1X1G

Hanau, 28.01.2025

Mjesto, datum / *Place, date*

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

Ime i funkcija / *Name and function*

MEGFELELŐSÉGI NYILATKOZAT / *DECLARATION OF CONFORMITY*

A vállalat neve és címe / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Németország / *Germany* *SRN: DE-MF-000007705*

Kizárólagos felelősségünkre kijelentjük, hogy / *We declare under our sole responsibility that*

az orvostechnikai eszköz / *the medical device*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
osztálya / *of class*	I
a következő szabály szerint / *according to rule*	5 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: Retraxil 01 verzió *Further Applied standards see Technical Documentation of Product Retraxil, Version 01*
Megfelelőségértékelési eljárás a következő szerint / *Conformity assessment procedure acc. to*	Az orvostechnikai eszközökről szóló, 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Bejelentett szervezet / *Notified Body*	-
Regisztrációs szám / *Registration number*:	-
Verziószám / *Version number*	01
Felváltja a megfelelőségi nyilatkozatot ettől / *Replaces Declaration of Conformity from*	-
Hanau, 28.01.2025 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.

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

Az orvostechnikai eszköz / *The medical device*	**Retraxil**
Verziószám / *Version number*	01
Felváltja a mellékletet ettől / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETRAXIL SAMPLE 1X1G

Hanau, 28.01.2025

Hely, dátum / *Place, date*

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

Név és funkció / *Name and function*

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*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
d'aicme / *of class*	I
de réir rialach / *according to rule*	5 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 Retraxil, Leagan 01 *Further Applied standards see Technical Documentation of Product Retraxil, Version* [01
Gnáthamh measúnaithe comhréireachta de réir / *Conformity assessment procedure acc. to*	Rialachán Feiste Leighis 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Comhlacht a dtugtar fógra dó / *Notified Body*	-
Uimhir chláraithe / *Registration number*:	-
Uimhir leagain / *Version number*	01
Tagann sé in áit Dearbhú Comhréireachta ó / *Replaces Declaration of Conformity from*	-
Hanau, 07.08.2024 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.*

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

An fheiste leighis / *The medical device*	**Retraxil**
Uimhir leagain / *Version number*	01
Tagann sé in áit Aguisín ó / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

Láthair, dáta / *Place, date*

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

Ainm agus feidhm / *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*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
di classe / *of class*	I
secondo la norma / *according to rule*	5 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 Retraxil, Versione [01 *Further Applied standards see Technical Documentation of Product Retraxil, Version* [01
Procedura di valutazione della conformità secondo il / *Conformity assessment procedure acc. to*	Regolamento sui dispositivi medici 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Organismo notificato / *Notified Body*	-
Numero di registrazione / *Registration number*:	-
Numero versione / *Version number*	01
Sostituisce la dichiarazione di conformità di / *Replaces Declaration of Conformity from*	-
Hanau, 07.08.2024 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*	**Retraxil**
Numero versione / *Version number*	01
Sostituisce l'allegato da / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

Luogo, data / *Place, date*

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

Nome e funzione / *Name and function*

DIKJARAZZJONI TA' KONFORMITÀ / *DECLARATION OF CONFORMITY*

Isem u indirizz tal-kumpanija / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Il-Ġermanja / *Germany* *SRN: DE-MF-000007705*

Niddikjaraw, taħt ir-responsabbiltà unika tagħna, li / *We declare under our sole responsibility that*

l-apparat mediku / *the medical device*	**Retraxil**
Isem, tip jew mudell, numru tal-lott jew tas-serje, possibbilment sorsi u numru ta' oġġetti / *Name, type or model, batch or serial number, possibly sources and number of items*	Lista ta' Oġġetti ara Anness / *List of Articles see Annex*
Kodiċi EMDN / *EMDN-Code* Kodiċi GMDN / *GMDN code* Kodiċi UMDNS / *UMDNS code* UDI-DI bażiku / *Basic UDI-DI*	Q010204 46423 - ++J0141209REP0204a3E
tal-klassi / *of class*	I
skont ir-regola / *according to rule*	5 skont l-Anness VIII tar-Regolament dwar l-Apparati Mediċi 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

jissodisfa d-dispożizzjonijiet kollha tar-Regolament dwar l-Apparati Mediċi 2017/745 li japplikaw għalih. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Standards armonizzati, standards nazzjonali jew dokumenti normativi oħra applikati / *Applied harmonised standards, national standards or other normative documents*	- Aktar Standards applikati ara d-Dokumentazzjoni Teknika ta' Prodott Retraxil, Verżjoni 01 *Further Applied standards see Technical Documentation of Product Retraxil, Version* [01
Proċedura tal-evalwazzjoni tal-konformità skont / *Conformity assessment procedure acc. to*	Regolament dwar Apparati Mediċi 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Korp Notifikat / *Notified Body*	-
Numru tar-reġistrazzjoni / *Registration number*:	-
Numru tal-verżjoni / *Version number*	01
Tissostitwixxi d-Dikjarazzjoni ta' Konformità ta' / *Replaces Declaration of Conformity from*	-
Hanau, 07.08.2024 Post, data / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Isem u funzjoni / *Name and function*

Din id-dikjarazzjoni ta' konformità hi valida għal sentejn b'rabta mad-dokumenti ta' rilaxx għal-lott rispettiv tal-apparati prodotti. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

Dikjarazzjoni ta' Konformità / *Declaration of Conformity*
Anness / *Annex*: Lista ta' Oġġetti / *List of Articles*

L-apparat mediku / *The medical device*	**Retraxil**
Numru tal-verżjoni / *Version number*	01
Jissostitwixxi l-Anness ta' / *Replaces Annex from*	-
Din il-lista ta' artikoli hija valida għad-dikjarazzjoni tal-verżjoni ta' konformità / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Numru tal-oġġett / *Article number***	**Isem / *Name***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

Post, data / *Place, date*

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

Isem u funzjoni / *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*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
van klasse / *of class*	I
in overeenstemming met regelgeving / *according to rule*	5 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 Retraxil versie 01 *Further Applied standards see Technical Documentation of Product Retraxil Version* [01
Conformiteitsbeoordelingsprocedure in overeenstemming met / *Conformity assessment procedure acc. to*	Verordening (EU) 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Aangemelde instantie / *Notified Body*	-
Registratienummer / *Registration number*:	-
Versienummer / *Version number*	01
Vervangt de verklaring van conformiteit van / *Replaces Declaration of Conformity from*	-

Hanau, 07.08.2024

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

Plaats, datum / *Place, date* — 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*	**Retraxil**
Versienummer / *Version number*	01
Vervangt de bijlage van / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

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*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
i klasse / *of class*	I
i henhold til regel / *according to rule*	5 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*	- Ytterligere anvendte standarder, se teknisk dokumentasjon for produktet Retraxil, versjon 01 *Further Applied standards see Technical Documentation of Product Retraxil, Version 01*
Prosedyre for samsvarsvurdering i henhold til / *Conformity assessment procedure acc. to*	forordning 2017/745 om medisinsk utstyr, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Teknisk kontrollorgan / *Notified Body*	-
Registreringsnummer / *Registration number*:	-
Versjonsnummer / *Version number*	01
Erstatter samsvarserklæring fra / *Replaces Declaration of Conformity from*	-
Hanau, 07.08.2024 Sted, dato / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Navn og funksjon / *Name and function*

Denne samsvarserklæringen er gyldig i 2 år i tilknytning til frigivelsesdokumentene for det aktuelle partiet med produsert utstyr / *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*	**Retraxil**
Versjonsnummer / *Version number*	01
Erstatter vedlegg fra / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

Sted, dato / *Place, date*

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

Navn og funksjon / *Name and function*

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*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
da classe / *of class*	I
em conformidade com o regulamento / *according to rule*	5 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 Retraxil Versão [01 *Further Applied standards see Technical Documentation of Product Retraxil Version* [01
Procedimento de avaliação da conformidade de acordo com / *Conformity assessment procedure acc. to*	Anexo IX do Regulamento 2017/745 Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Organismo notificado / *Notified Body*	-
Número de registo / *Registration number*:	-
Número de versão / *Version number*	01
Substitui a Declaração de Conformidade de / *Replaces Declaration of Conformity from*	-

Hanau, 07.08.2024

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.*

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

O dispositivo médico / *The medical device*	**Retraxil**
Número de versão / *Version number*	01
Substitui o Anexo de / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

Local, data / *Place, date*

i.V.

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

Nome e função / *Name and function*

DECLARAȚIE DE CONFORMITATE / *DECLARATION OF CONFORMITY*

Numele și adresa companiei / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Germania / *Germany* *SRN: DE-MF-000007705*

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

dispozitivul medical / *the medical device*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
din clasa / *of class*	I
în conformitate cu regula / *according to rule*	5 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 Retraxil Versiunea 01 *Further Applied standards see Technical Documentation of Product Retraxil, Version 01*
Procedură de evaluare a conformității în conf. cu / *Conformity assessment procedure acc. to*	Regulamentul privind dispozitivele medicale 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Organism notificat / *Notified Body*	-
Numărul de înregistrare / *Registration number*:	-
Număr versiune / *Version number*	01
Înlocuiește Declarația de conformitate din / *Replaces Declaration of Conformity from*	-
Hanau, 28.01.2025	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Loc, dată / *Place, date*	Nume și funcție / *Name and function*

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

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

Dispozitivul medical / *The medical device*	**Retraxil**
Număr versiune / *Version number*	01
Înlocuiește Anexa de la / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETRAXIL SAMPLE 1X1G

Hanau, 28.01.2025

Loc, dată / *Place, date*

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

Nume și funcție / *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*	**Retraxil**
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*	Q010204 46423 - ++J0141209REP0204a3E
i klass / *of class*	I
enligt paragraf / *according to rule*	5 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 Retraxil, version 01 *Further Applied standards see Technical Documentation of Product Retraxil, Version* [01
Förfarande för bedömning av överensstämmelse enl. / *Conformity assessment procedure acc. to*	förordning om medicintekniska 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Anmält organ / *Notified Body*	-
Registreringsnummer / *Registration number*:	-
Versionsnummer / *Version number*	01
Ersätter försäkran om överensstämmelse från / *Replaces Declaration of Conformity from*	-
Hanau, 07.08.2024 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*	**Retraxil**
Versionsnummer / *Version number*	01
Ersätter bilaga från / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETAXIL SAMPLE 1X1G

Hanau, 07.08.2024

Ort, datum / *Place, date*

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

Namn och funktion / *Name and function*

IZJAVA O SKLADNOSTI / *DECLARATION OF CONFORMITY*

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

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

medicinski pripomoček / *the medical device*	**Retraxil**
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*	Q010204
Koda GMDN / *GMDN code*	46423
Koda UMDNS / *UMDNS code*	-
Osnovni UDI-DI / *Basic UDI-DI*	++J0141209REP0204a3E
razreda / *of class*	I
v skladu s členom / *according to rule*	5 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 Retraxil, različica 01 *Further Applied standards see Technical Documentation of Product Retraxil, Version 01*
Postopek ugotavljanja skladnosti v skladu z / *Conformity assessment procedure acc. to*	Uredbo o medicinskih pripomočkih 2017/745, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Priglašeni organ / *Notified Body*	-
Registrska številka / *Registration number*:	-
Številka različice / *Version number*	01
Nadomešča Izjavo o skladnosti z dne / *Replaces Declaration of Conformity from*	-
Hanau, 28.01.2025	zastopnica Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Kraj, datum / *Place, date*	Ime in položaj / *Name and function*

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

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

Medicinski pripomoček / *The medical device*	**Retraxil**
Številka različice / *Version number*	01
Nadomešča Prilogo z dne / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETRAXIL SAMPLE 1X1G

Hanau, 28.01.2025

Kraj, datum / *Place, date*

i.V.

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

Ime in položaj / *Name and function*

VYHLÁSENIE O ZHODE / *DECLARATION OF CONFORMITY*

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

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

zdravotnícka pomôcka / *the medical device*	**Retraxil**
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*	Q010204
Kód GMDN / *GMDN code*	46423
Kód UMDNS / *UMDNS code*	-
Základné identifikačné číslo UDI-DI / *Basic UDI-DI*	++J0141209REP0204a3E
triedy / *of class*	I
podľa pravidla / *according to rule*	5 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 01 k produktu Retraxil *Further Applied standards see Technical Documentation of Product Retraxil, Version 01*
Postup posúdenia zhody podľa / *Conformity assessment procedure acc. to*	nariadeniu 2017/745 o zdravotníckych pomôckach, Art 52 (7) *Medical Device Regulation 2017/745, Art 52 (7)*
Notifikovaný orgán / *Notified Body*	-
Registračné číslo / *Registration number*:	-
Číslo verzie / *Version number*	01
Nahrádza vyhlásenie o zhode z / *Replaces Declaration of Conformity from*	-
Hanau, 28.01.2025 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.*

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

Zdravotnícka pomôcka / *The medical device*	**Retraxil**
Číslo verzie / *Version number*	01
Nahrádza prílohu z / *Replaces Annex from*	-
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***
+J014660981800	66098180	RETRAXIL STARTER PACK 4X1 G
+J014660981790	66098179	RETRAXIL VALUE PACK 20X1G
+J014660987210	66098721	RETRAXIL SAMPLE 1X1G

Hanau, 28.01.2025

Miesto, dátum / *Place, date*

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

Meno a funkcia / *Name and function*