KULZER
MITSUI CHEMICALS GROUP

KONFORMITÄTSERKLÄRUNG / *DECLARATION OF CONFORMITY*

Name und Adresse der Firma / *Name and address of the company*	**Kulzer GmbH** Leipziger Straße 2, 63450 Hanau Deutschland / *Germany* *SRN: DE-MF-000007705*

Wir erklären in alleiniger Verantwortung, dass / *We declare under our sole responsibility that*

das Medizinprodukt / *the medical device*	**Variotime**
Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl / *Name, type or model, batch or serial number, possibly sources and number of items*	Artikelliste siehe Anhang / *List of Articles see Annex*
EMDN-Nummer / *EMDN-Code* GMDN-Nummer / *GMDN code* UMDNS-Nummer / *UMDNS code* Basis-UDI-DI / *Basic UDI-DI*	Q010201 35866 16-679 ++J0141209IMA0201aTU
der Klasse / *of class*	IIa
nach Regel / *according to rule*	5-1, 19-3 nach Anhang VIII der Medizinprodukte-Verordnung, 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

allen Anforderungen der Medizinprodukte-Verordnung 2017/745 entspricht, die anwendbar sind / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - Zahnheilkunde – Elastomere Abform- und Bissregistriermaterialien / *Dentistry – Elastomeric impression and bite registration materials* Weitere angewandte Normen siehe Version 02 der Technischen Dokumentation von Flexitime / Variotime / *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version 02*
Konformitätsbewertungsverfahren nach / *Conformity assessment procedure acc. to*	Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I, Abschnitt 2 und 3 and Kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Benannte Stelle / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Germany CE 0197
Registrierungsnr. / *Registration No.*:	HZ 1198082-1
Versionsnummer / *Version number*	02
Ersetzt Konformitätserklärung vom / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hanau, 13.03.2025 Ort, Datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Name und Funktion / *Name and function*

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

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

das Medizinprodukt / *for the medical device*	**Variotime**
Versionsnummer Artikelliste/ *Version number article list*	03
Ersetzt Artikelliste vom / *Replaces article list from*	V02, 17.11.2023
Diese Artikelliste ist gültig für die Konformitätserklärung Version/ *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hanau, 13.03.2025

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*	**Variotime**
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*	Q010201 35866 16-679 ++J0141209IMA0201aTU
от клас / *of class*	IIa
съгласно правило / *according to rule*	5-1, 19-3 съгласно Приложение VIII от Регламента за медицинските изделия 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Приложени хармонизирани стандарти, национални стандарти или други нормативни документи / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Други приложени стандарти, вижте техническата документация на продукт Flexitime / Variotime Версия 02 *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version 02*
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*	02
Заменя Декларация за съответствие от / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Ханау, 13.03.2025 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*	**Variotime**
Номер на версия / *Version number*	03
Заменя Приложението от / *Replaces Annex from*	V02, 17.11.2023
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*	02

UDI-DI / *UDI-DI*	**Номер на артикул / *Article number***	**Наименование / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Ханау, 13.03.2025

Място, дата / *Place, date*

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

Име и длъжност / *Name and function*

PROHLÁŠENÍ O SHODĚ / *DECLARATION OF CONFORMITY*

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

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

zdravotnický prostředek / *the medical device*	**Variotime**
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*	Q010201 35866 16-679 ++J0141209IMA0201aTU
třídy / *of class*	IIa
podle pravidla / *according to rule*	5-1, 19-3 podle přílohy VIII k nařízení 2017/745 o zdravotnických prostředcích / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Použité harmonizované normy, národní normy nebo jiné normativní dokumenty / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Další použité normy najdete v technické dokumentaci k výrobku Flexitime / Variotime, verze 02 *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version 02*
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*	02
Nahrazuje Prohlášení o shodě ze dne / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hanau, 13.03.2025	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*.

KULZER
MITSUI CHEMICALS GROUP

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

Zdravotnický prostředek / *The medical device*	**Variotime**
Číslo verze / *Version number*	03
Nahrazuje přílohu ze dne / *Replaces Annex from*	V02, 17.11.2023
Tento seznam zboží platí pro verzi prohlášení o shodě / *This article list is valid for the declaration of conformity version:*	02

UDI-DI / *UDI-DI*	**Číslo zboží / *Article number***	**Název / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hanau, 13.03.2025

Místo, datum / *Place, date*

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

Jméno a funkce / *Name and function*

VASTAVUSDEKLARATSIOON / *DECLARATION OF CONFORMITY*

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

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

meditsiiniseade / *the medical device*	**Variotime**
Nimi, tüüp või mudel, partii või seerianumber, võimalikud allikad ja osad / *Name, type or model, batch or serial number, possibly sources and number of items*	Artiklite loendit vt lisast / *List of Articles see Annex*
EMDN-kood / *EMDN-Code* GMDN-i kood / *GMDN code* UMDNS-i kood / *UMDNS code* Põhi-UDI-DI / *Basic UDI-DI*	Q010201 35866 16-679 ++J0141209IMA0201aTU
klassil / *of class*	IIa
kooskõlas reegliga / *according to rule*	5-1, 19-3 kooskõlas meditsiiniseadme määrusega 2017/745 lisaga VIII / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Kehtivad harmoniseeritud standardid, riiklikud standardid ja muud normatiivdokumendid / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Muid rakenduvaid standardeid vt tehnilistest dokumentidest tootele Flexitime / Variotime, Version 02 *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version 02*
Vastavushindamismenetlus vastavalt / *Conformity assessment procedure acc. to*	meditsiiniseadmete määruse 2017/745 IX. lisa, I. peatükk, 2. ja 3. jaotis ning III. peatükk *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Teavitatud asutus / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Saksamaa CE 0197
Registreerimisnumber / *Registration number*:	HZ 1198082-1
Versiooni number / *Version number*	02
Asendab vastavusdeklaratsiooni alates / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hanau, 13.03.2025 Koht, kuupäev / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nimi ja funktsioon / *Name and function*

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

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

Meditsiiniseade / *The medical device*	**Variotime**
Versiooni number / *Version number*	03
Asendab lisa alates / *Replaces Annex from*	V02, 17.11.2023
See artiklite loend kehtib vastavusdeklaratsiooni versiooni kohta / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Artikli number / *Article number***	**Nimi / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hanau, 13.03.2025

Koht, kuupäev / *Place, date*

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

Nimi ja funktsioon / *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*	**Variotime**
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*	Q010201 35866 16-679 ++J0141209IMA0201aTU
κλάσης / *of class*	IIa
σύμφωνα με τον κανόνα / *according to rule*	5-1, 19-3 σύμφωνα με το Παράρτημα VIII του Κανονισμού 2017/745 για τα ιατροτεχνολογικά προϊόντα / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Εφαρμοζόμενα εναρμονισμένα πρότυπα, εθνικά πρότυπα ή άλλα κανονιστικά έγγραφα / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική τεκμηρίωση του προϊόντος Flexitime / Variotime, έκδοση 02 *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version 02*
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*	02
Αντικαθιστά τη δήλωση συμμόρφωσης από / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hanau, 13.03.2025	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Τόπος, ημερομηνία / *Place, date*	Ονοματεπώνυμο και τίτλος / *Name and function*

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

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

Το ιατροτεχνολογικό προϊόν / *The medical device*	**Variotime**
Αριθμός έκδοσης / *Version number*	03
Αντικαθιστά το Παράρτημα από / *Replaces Annex from*	V02, 17.11.2023
Αυτός ο κατάλογος προϊόντων ισχύει για την έκδοση δήλωσης συμμόρφωσης / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Αριθμός είδους / *Article number***	**Όνομα / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
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+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hanau, 13.03.2025

Τόπος, ημερομηνία / *Place, date*

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

Ονοματεπώνυμο και τίτλος / *Name and function*

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*	**Variotime**
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*	Q010201 35866 16-679 ++J0141209IMA0201aTU
osztálya / *of class*	IIa
a következő szabály szerint / *according to rule*	5-1, 19-3 az orvostechnikai eszközökről szóló 2017/745 rendelet VIII. melléklete szerint / *according to Annex VIII of Medical Device Regulation 2017/745*

megfelel az orvostechnikai eszközökről szóló, 2017/745 rendelet valamennyi rá vonatkozó rendelkezésének. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Alkalmazott harmonizált szabványok, nemzeti szabványok vagy más normatív dokumentumok / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* További alkalmazott szabványokat lásd a műszaki dokumentációban, termék: Flexitime / Variotime, 02. verzió *Further Applied standards see Technical Documentation of Flexitime / Variotime*, Version *02*
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*	02
Felváltja a megfelelőségi nyilatkozatot ettől / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hanau, 13.03.2025 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.

KULZER
MITSUI CHEMICALS GROUP

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

Az orvostechnikai eszköz / *The medical device*	**Variotime**
Verziószám / *Version number*	03
Felváltja a mellékletet ettől / *Replaces Annex from*	V02, 17.11.2023
Ez a tétellista a megfelelőségi nyilatkozat következő verziójához érvényes / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Cikkszám / *Article number***	**Név / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hanau, 13.03.2025

Hely, dátum / *Place, date*

i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH
Név és funkció / *Name and function*

KULZER
MITSUI CHEMICALS GROUP

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*	**Variotime**
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*	Q010201 35866 16-679 ++J0141209IMA0201aTU
klasės / *of class*	IIa
pagal taisyklę / *according to rule*	5-1, 19-3 Pagal Medicinos prietaisų reglamento 2017/745 VIII priedą / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Taikomi harmonizuotieji standartai, nacionaliniai standartai ar kiti normatyviniai dokumentai / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* atkuriamosiomis medžiagomis Kitus taikomus standartus žr. produkto Flexitime / Variotime, techninėje dokumentacijoje, 02 versijoje *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version 02*
]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*	02
Pakeičia atitikties deklaraciją nuo / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hanau, 13.03.2025	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Vieta, data / *Place, date*	Vardas, pavardė ir pareigos / *Name and function*

Ši atitikties deklaracija galioja 2 metus kartu su atitinkamos pagamintų priemonių partijos pateikimo į rinką dokumentais. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*

KULZER
MITSUI CHEMICALS GROUP

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

Medicinos prietaisas / *The medical device*	**Variotime**
Versijos numeris / *Version number*	03
Pakeičia Priedą nuo / *Replaces Annex from*	V02, 17.11.2023
Šis straipsnių sąrašas tinka atitikties deklaracijai, kurios versija yra / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Prekės numeris / *Article number***	**Pavadinimas / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hanau, 13.03.2025

Vieta, data / *Place, date*

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

Vardas, pavardė ir pareigos / *Name and function*

ATBILSTĪBAS DEKLARĀCIJA / *DECLARATION OF CONFORMITY*

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

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

medicīniskā ierīce / *the medical device*	**Variotime**
Preču nosaukums, tips vai modelis, partijas vai sērijas numurs, iespējamie avoti un skaits / *Name, type or model, batch or serial number, possibly sources and number of items*	Preču sarakstu skatiet pielikumā / *List of Articles see Annex*
EMDN kods / *EMDN-Code* GMDN kods / *GMDN code* UMDNS kods / *UMDNS code* Pamata UDI-DI / *Basic UDI-DI*	Q010201 35866 16-679 ++J0141209IMA0201aTU
klase / *of class*	IIa
saskaņā ar noteikumu / *according to rule*	5-1, 19-3 saskaņā ar Medicīnisko ierīču regulas 2017/745 VIII pielikumu / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Izmantotie saskaņotie standarti, nacionālie standarti vai citi normatīvie dokumenti / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Citus izmantotos standartus skatiet tehniskajā dokumentācijā par produktu Flexitime / Variotime, 02. versija *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version 02*
Atbilstības novērtēšanas procedūra saskaņā ar / *Conformity assessment procedure acc. to*	Medicīnisko ierīču regulas 2017/745 IX pielikumu, I nodaļu, 2. un 3. iedaļu un III nodaļu *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Pilnvarotā iestāde / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Vācija CE 0197
Reģistrācijas numurs / *Registration number*:	HZ 1198082-1
Versijas numurs / *Version number*	02
Aizstāj atbilstības deklarāciju, kas datēta ar / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hānava 13.03.2025 Vieta, datums / *Place, date*	i.V. v.i. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Vārds, uzvārds un amats / *Name and function*

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

KULZER
MITSUI CHEMICALS GROUP

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

Medicīniskā ierīce / *The medical device*	**Variotime**
Versijas numurs / *Version number*	03
Aizstāj pielikumu, kas datēts ar / *Replaces Annex from*	V02, 17.11.2023
Šis izstrādājumu saraksts ir derīgs šādai atbilstības deklarācijas versijai / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Preces numurs / *Article number***	**Nosaukums / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hānava 13.03.2025

Vieta, datums / *Place, date*

i.V.

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

Vārds, uzvārds un amats / *Name and function*

DEKLARACJA ZGODNOŚCI / *DECLARATION OF CONFORMITY*

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

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

wyrób medyczny / *the medical device*	**Variotime**
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*	Q010201 35866 16-679 ++J0141209IMA0201aTU
klasy / *of class*	IIa
zgodnie z regułą / *according to rule*	5-1, 19-3 zgodnie z załącznikiem VIII do Rozporządzenia 2017/745 w sprawie wyrobów medycznych / *according to Annex VIII of Medical Device Regulation 2017/745*

spełnia wszystkie przepisy Rozporządzenia 2017/745 w sprawie wyrobów medycznych, które go dotyczą. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Zastosowane normy zharmonizowane, normy krajowe lub inne dokumenty normatywne / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Pozostałe stosowane normy znajdują się w dokumentacji technicznej produktu Flexitime / Variotime, wersja 02 *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version* 02
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*	02
Zastępuje Deklarację zgodności z / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hanau, 13.03.2025	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH**
Miejscowość, data / *Place, date*	Imię i nazwisko, stanowisko / *Name and function*

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

KULZER
MITSUI CHEMICALS GROUP

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

Wyrób medyczny / *The medical device*	**Variotime**
Numer wersji / *Version number*	03
Zastępuje załącznik z dnia / *Replaces Annex from*	V02, 17.11.2023
Poniższa lista artykułów obowiązuje dla następujących wersji deklaracji zgodności / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Numer wyrobu / *Article number***	**Nazwa / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hanau, 13.03.2025

Miejscowość, data / *Place, date*

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

Imię i nazwisko, stanowisko / *Name and function*

DECLARAȚIE DE CONFORMITATE / *DECLARATION OF CONFORMITY*

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

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

dispozitivul medical / *the medical device*	**Variotime**
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*	Q010201 35866 16-679 ++J0141209IMA0201aTU
din clasa / *of class*	IIa
în conformitate cu regula / *according to rule*	5-1, 19-3 conform Anexei VIII la Regulamentul privind dispozitivele medicale 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Standarde armonizate, naționale aplicate sau alte documente normative / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Alte standarde aplicate, vezi documentația tehnică a Produsului Flexitime / Variotime, Versiunea 02 *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version 02*
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*	02
Înlocuiește Declarația de conformitate din / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hanau, 13.03.2025 Loc, dată / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nume și funcție / *Name and function*

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*	**Variotime**
Număr versiune / *Version number*	03
Înlocuiește Anexa de la / *Replaces Annex from*	V02, 17.11.2023
Această listă de articole este valabilă pentru declarația de conformitate versiunea / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Număr articol / *Article number***	**Nume / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hanau, 13.03.2025

Loc, dată / *Place, date*

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

Nume și funcție / *Name and function*

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*	**Variotime**
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*	Q010201 35866 16-679 ++J0141209IMA0201aTU
razreda / *of class*	IIa
v skladu s členom / *according to rule*	5-1, 19-3, v skladu s Prilogo VIII Uredbe o medicinskih pripomočkih 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Uveljavljeni usklajeni standardi, nacionalni standardi ali drugi normativni dokumenti / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Drugi uveljavljeni standardi so na voljo v Tehnični dokumentaciji izdelka Flexitime / Variotime, različica 02 *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version 02*
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*	02
Nadomešča Izjavo o skladnosti z dne / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hanau, 13.03.2025 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*

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.*

KULZER
MITSUI CHEMICALS GROUP

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

Medicinski pripomoček / *The medical device*	**Variotime**
Številka različice / *Version number*	03
Nadomešča Prilogo z dne / *Replaces Annex from*	V02, 17.11.2023
Ta seznam izdelkov velja za naslednjo različico izjave o skladnosti / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Številka artikla / *Article number***	**Ime / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hanau, 13.03.2025

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*	**Variotime**
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*	Q010201 35866 16-679 ++J0141209IMA0201aTU
triedy / *of class*	IIa
podľa pravidla / *according to rule*	5-1, 19-3 podľa prílohy VIII k nariadeniu 2017/745 o zdravotníckych pomôckach / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Použité harmonizované normy, národné normy alebo iné normatívne dokumenty / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Ďalšie použité normy nájdete v technickej dokumentácii verzie 02 k produktu Flexitime / Variotime *Further Applied standards see Technical Documentation of Flexitime / Variotime, Version 02*
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*	02
Nahrádza vyhlásenie o zhode z / *Replaces Declaration of Conformity from*	V01, 01.11.2023
Hanau, 13.03.2025 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.

KULZER
MITSUI CHEMICALS GROUP

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

Zdravotnícka pomôcka / *The medical device*	**Variotime**
Číslo verzie / *Version number*	03
Nahrádza prílohu z / *Replaces Annex from*	V02, 17.11.2023
Tento zoznam tovaru je platný pre vyhlásenie o zhode, verzia / *This article list is valid for the declaration of conformity version*	02

UDI-DI / *UDI-DI*	**Číslo položky / *Article number***	**Meno / *Name***
+J014660450380	66045038	Variotime Light Flow 2x50 mL
+J014660450400	66045040	Variotime Extra Light Flow 2x50 mL
+J014660450360	66045036	Variotime Medium Flow 2x50 mL
+J014660450320	66045032	Variotime Monophase 2x50 mL
+J014660449980	66044998	Variotime Heavy Tray 2x50 mL
+J014660449930	66044993	Variotime Easy Putty 1x600 mL
+J014660450340	66045034	Variotime Dynamix Monophase 2x380 mL
+J014660450000	66045000	Variotime Dynamix Heavy Tray 2x380 mL
+J014660449950	66044995	Variotime Dynamix Putty 2x380 mL
+J014660780170	66078017	Variotime Monophase 1x50 mL SAMPLE
+J014660450440	66045044	Variotime Easy Putty & Flow Kit
+J014660993220	66099322	Variotime unlimited Dynamix Refill (1x2x380ml)
+J014660993230	66099323	Variotime unlimited 1x(2x50ml)
+J014660993240	66099324	Variotime unlimited Dynamix Trial Kit
+J014660993250	66099325	Variotime unlimited 1x50ml Sample
+J014660993260	66099326	Variotime unlimited Trial Kit

Hanau, 13.03.2025

Miesto, dátum / *Place, date*

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

Meno a funkcia / *Name and function*