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*	**Provil Novo**
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 ++J0141209IMA0201eU4
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 1 der Technischen Dokumentation von Product Provil Novo / *Further Applied standards see Technical Documentation of Provil Novo, Version 1*
Konformitätsbewertungsverfahren nach / *Conformity assessment procedure acc. to*	Medizinprodukte-Verordnung 2017/745 Anhang IX, Kapitel I, Abschnitt 2 und 3 and Kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Benannte Stelle / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Germany CE 0197
Registrierungsnr. / *Registration No.*:	HZ 1198082-1
Versionsnummer / *Version number*	01
Ersetzt Konformitätserklärung vom / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 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.*

KULZER
MITSUI CHEMICALS GROUP

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

das Medizinprodukt / *for the medical device*	**Provil Novo**
Versionsnummer Artikelliste/ *Version number article list*	01
Ersetzt Artikelliste vom / *Replaces article list from*	N/A
Diese Artikelliste ist gültig für die Konformitätserklärung Version/ *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Name / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
+J014660464740	66046474	Provil Novo P Reg 1x900
+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

Hanau, 01.11.2023

Ort, Datum / *Place, date*

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

Name und Funktion / *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*	**Provil Novo**
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 ++J0141209IMA0201eU4
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 Provil Novo, verze 1 *Further Applied standards see Technical Documentation of Provil Novo, Version 1*
Procedura posouzení shody podle / *Conformity assessment procedure acc. to*	nařízení 2017/745 o zdravotnických prostředcích, příloha IX, kapitola I, oddíl 2 a 3 a kapitola III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Notifikovaná osoba / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Německo CE 0197
Registrační číslo / *Registration number*:	HZ 1198082-1
Číslo verze / *Version number*	01
Nahrazuje Prohlášení o shodě ze dne / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023	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*	**Provil Novo**
Číslo verze / *Version number*	01
Nahrazuje přílohu ze dne / *Replaces Annex from*	N/A
Tento seznam zboží platí pro verzi prohlášení o shodě / *This article list is valid for the declaration of conformity version:*	01

UDI-DI / *UDI-DI*	**Číslo zboží / *Article number***	**Název / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
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+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

Hanau, 01.11.2023

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*	**Provil Novo**
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*	Q010201 35866 16-679 ++J0141209IMA0201eU4
i klasse / *of class*	IIa
i henhold til artikel / *according to rule*	5-1, 19-3 i bilag VIII i Europa-Parlamentets og Rådets forordning (EU) 2017/745 om medicinsk udstyr / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Anvendte harmoniserede standarder, nationale standarder eller andre normative dokumenter / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Andre anvendte standarder kan ses i det tekniske dokumentationsmateriale til produktet Provil Novo, version 1 *Further Applied standards see Technical Documentation of Provil Novo, Version 1*
Overensstemmelsesvurderingsprocedure iht. / *Conformity assessment procedure acc. to*	Forordning (EU) 2017/745 om medicinsk udstyr, bilag IX, kapitel I, afsnit 2 og 3 samt kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Underrettet organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 D-90431 Nürnberg, Tyskland CE 0197
Registreringsnummer / *Registration number*:	HZ 1198082-1
Versionsnummer / *Version number*	01
Erstatter overensstemmelseserklæring fra / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 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.*

KULZER
MITSUI CHEMICALS GROUP

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

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

UDI-DI / *UDI-DI*	**Varenummer / *Article number***	**Betegnelse / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
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+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
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+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
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+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

Hanau, 01.11.2023

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*	**Provil Novo**
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*	Q010201 35866 16-679 ++J0141209IMA0201eU4
de la clase / *of class*	IIa
de acuerdo con la norma / *according to rule*	5-1, 19-3 de acuerdo con el Anexo VIII del Reglamento sobre productos sanitarios 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

cumple todas las disposiciones del Reglamento sobre productos sanitarios 2017/745 que se le aplican. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Normas armonizadas, normas nacionales u otros documentos normativos que se aplican / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 *Dentistry – Elastomeric impression and bite registration materials* Para otras normas aplicadas consulte la documentación técnica del producto Provil Novo, versión 01 *Further Applied standards see Technical Documentation of Provil Novo, Version 01*
Procedimiento de evaluación de la conformidad de acuerdo con / *Conformity assessment procedure acc. to*	Reglamento sobre productos sanitarios 2017/745 Anexo IX, Capítulo I, Secciones 2 y 3 y Capítulo III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organismo notificado / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Alemania CE 0197
Número de registro / *Registration number*:	HZ 1198082-1
Número de versión / *Version number*	01
Sustituye a la declaración de conformidad del / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Lugar, fecha / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Nombre y cargo / *Name and function*

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

KULZER
MITSUI CHEMICALS GROUP

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

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

UDI-DI / *UDI-DI*	**Número de artículo / *Article number***	**Nombre / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
+J014660464740	66046474	Provil Novo P Reg 1x900
+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

i.V.

Hanau, 01.11.2023

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*	**Provil Novo**
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*	Q010201 35866 16-679 ++J0141209IMA0201eU4
luokka / *of class*	IIa
säädös / *according to rule*	5-1, 19-3 lääkinnällisistä laitteista annetun asetuksen 2017/745 liitteen VIII mukaan / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Soveltuvat harmonisoidut standardit, kansalliset standardit tai muut säädökset / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Muut sovellettavat standardit, ks. tekniset tiedot tuotteesta Provil Novo, versio 1 *Further Applied standards see Technical Documentation of Provil Novo, Version 1*
Vaatimustenmukaisuuden arviointimenettelyn perusta / *Conformity assessment procedure acc. to*	Asetus lääkinnällisistä laitteista 2017/745, liite IX, I luku, 2 ja 3 kohta ja III luku *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Ilmoitettu laitos / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Saksa CE 0197
Rekisteröintinumero / *Registration number*:	HZ 1198082-1
Versionumero / *Version number*	01
Korvaa vaatimustenmukaisuusvakuutuksen / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Paikka, päiväys / *Place, date*	i.V. 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*	**Provil Novo**
Versionumero / *Version number*	01
Korvaa liitteen / *Replaces Annex from*	N/A
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***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
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+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
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+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

Hanau, 01.11.2023

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*	**Provil Novo**
Nom, type ou modèle, numéro de lot ou de série, éventuellement sources et nombre d'articles / *Name, type or model, batch or serial number, possibly sources and number of items*	Liste des articles voir l'Annexe / *List of Articles see Annex*
Code EMDN / *EMDN-Code* Code GMDN / *GMDN code* Code UMDNS / *UMDNS code* UDI-DI de base / *Basic UDI-DI*	Q010201 35866 16-679 ++J0141209IMA0201eU4
de classe / *of class*	IIa
selon la règle / *according to rule*	5-1, 19-3 conformément à l'Annexe VIII du Règlement des Dispositifs Médicaux 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Application de normes harmonisées, de normes nationales ou d'autres documents normatifs / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Autres normes appliquées voir Documentation technique du produit Provil Novo, version 1 *Further Applied standards see Technical Documentation of Provil Novo, Version 1*
Procédure d'évaluation de la conformité selon / *Conformity assessment procedure acc. to*	Règlement relatif aux dispositifs médicaux 2017/745 Annexe IX, Chapitre I, Paragraphes 2 et 3 et Chapitre III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organisme notifié / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Allemagne CE 0197
Numéro d'enregistrement / *Registration number*:	HZ 1198082-1
Numéro de version / *Version number*	01
Remplace la Déclaration de conformité de / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 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.*

KULZER
MITSUI CHEMICALS GROUP

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

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

UDI-DI / *UDI-DI*	**Numéro de référence / *Article number***	**Nom / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
+J014660464740	66046474	Provil Novo P Reg 1x900
+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

i.V. Matthias Hartmann

Hanau, 01.11.2023

Lieu, date / *Place, date*

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

Nom et fonction / *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*	**Provil Novo**
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*	Q010201 35866 16-679 ++J0141209IMA0201eU4
d'aicme / *of class*	IIa
de réir rialach / *according to rule*	5-1, 19-3 de réir Aguisín VIII de Rialachán Feiste Leighis 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Caighdeáin chomhoiriúnaithe i bhfeidhm, caighdeáin náisiúnta nó cáipéisí normatacha eile / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 *Dentistry – Elastomeric impression and bite registration materials* Féach Cáipéisíocht Theicniúil do Chaighdeáin Bhreise i bhfeidhm ar Táirge Provil Novo,, Leagan 01 / *Further Applied standards see Technical Documentation of Provil Novo,, Version 01*
Gnáthamh measúnaithe comhréireachta de réir / *Conformity assessment procedure acc. to*	Rialachán Feiste Leighis 2017/745 Iarscríbhinn IX, Caibidil I, Alt 2 agus 3 agus Caibidil III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Comhlacht a dtugtar fógra dó / *Notified Body*	TÜV Rheinland LGA Táirgí GmbH Tillystrasse 2 90431 Nürnberg / An Ghearmáin CE 0197
Uimhir chláraithe / *Registration number*:	HZ 1198082-1
Uimhir leagain / *Version number*	01
Tagann sé in áit Dearbhú Comhréireachta ó / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 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.*

KULZER
MITSUI CHEMICALS GROUP

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

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

UDI-DI / *UDI-DI*	**Uimhir airteagail / *Article number***	**Ainm / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
+J014660464740	66046474	Provil Novo P Reg 1x900
+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

Hanau, 01.11.2023

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*	**Provil Novo**
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*	Q010201 35866 16-679 ++J0141209IMA0201eU4
di classe / *of class*	IIa
secondo la norma / *according to rule*	5-1, 19-3 secondo l'allegato VIII del regolamento sui dispositivi medici 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Norme armonizzate applicate, norme nazionali o altri documenti normativi / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Ulteriori norme applicate vedi Documentazione tecnica di Prodotto Provil Novo, Versione 1 *Further Applied standards see Technical Documentation of Provil Novo, Version 1*
Procedura di valutazione della conformità secondo il / *Conformity assessment procedure acc. to*	Regolamento sui dispositivi medici 2017/745 Allegato IX, Capitolo I, Paragrafi 2 e 3, e Capitolo III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organismo notificato / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Norimberga / Germania CE 0197
Numero di registrazione / *Registration number*:	HZ 1198082-1
Numero versione / *Version number*	01
Sostituisce la dichiarazione di conformità di / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 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*	**Provil Novo**
Numero versione / *Version number*	01
Sostituisce l'allegato da / *Replaces Annex from*	N/A
Questa lista di articoli è valida per la versione della dichiarazione di conformità / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Numero articolo / *Article number***	**Nome / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
+J014660464740	66046474	Provil Novo P Reg 1x900
+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

Hanau, 01.11.2023

Luogo, data / *Place, date*

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

Nome e funzione / *Name and function*

VERKLARING VAN CONFORMITEIT / *DECLARATION OF CONFORMITY*

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

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

het medisch hulpmiddel / *the medical device*	**Provil Novo**
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*	Q010201 35866 16-679 ++J0141209IMA0201eU4
van klasse / *of class*	IIa
in overeenstemming met regelgeving / *according to rule*	5-1, 19-3 conform Bijlage VIII van de Verordening (EU) 2017/745 betreffende medische hulpmiddelen / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Toegepaste geharmoniseerde normen, nationale normen of andere normatieve documenten / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 *Dentistry – Elastomeric impression and bite registration materials* Voor overige toegepaste normen, zie technische documenten van product Provil Novo, versie 01 *Further Applied standards see Technical Documentation of Provil Novo, Version 01*
Conformiteitsbeoordelingsprocedure in overeenstemming met / *Conformity assessment procedure acc. to*	Verordening (EU) 2017/745 betreffende medische hulpmiddelen bijlage IX, hoofdstuk I, sectie 2 en 3 en hoofdstuk III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Aangemelde instantie / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Duitsland CE 0197
Registratienummer / *Registration number*:	HZ 1198082-1
Versienummer / *Version number*	01
Vervangt de verklaring van conformiteit van / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Plaats, datum / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Naam en functie / *Name and function*

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

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

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

Unieke identificatiecode / *UDI-DI*	**Artikelnummer / *Article number***	**Naam / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
+J014660464740	66046474	Provil Novo P Reg 1x900
+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

Hanau, 01.11.2023

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*	**Provil Novo**
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*	Q010201 35866 16-679 ++J0141209IMA0201eU4
i klasse / *of class*	IIa
i henhold til regel / *according to rule*	5-1, 19-3 i henhold til vedlegg VIII i forordning 2017/745 om medisinsk utstyr / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Anvendte harmoniserte standarder, nasjonale standarder eller andre normative dokumenter / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Ytterligere anvendte standarder, se teknisk dokumentasjon for produktet Provil Novo, versjon 1 *Further Applied standards see Technical Documentation of Provil Novo, Version 1*
Prosedyre for samsvarsvurdering i henhold til / *Conformity assessment procedure acc. to*	forordning 2017/745 om medisinsk utstyr vedlegg IX, kapittel I, avsnitt 2 og 3 og kapittel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Teknisk kontrollorgan / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Tyskland CE 0197
Registreringsnummer / *Registration number*:	HZ 1198082-1
Versjonsnummer / *Version number*	01
Erstatter samsvarserklæring fra / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 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*	**Provil Novo**
Versjonsnummer / *Version number*	01
Erstatter vedlegg fra / *Replaces Annex from*	N/A
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***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
+J014660464740	66046474	Provil Novo P Reg 1x900
+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

i.V.

Hanau, 01.11.2023

Sted, dato / *Place, date*

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

Navn og funksjon / *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*	**Provil Novo**
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 ++J0141209IMA0201eU4
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 Provil Novo, wersja 1 *Further Applied standards see Technical Documentation of Provil Novo, Version 1*
Procedura oceny zgodności wg. / *Conformity assessment procedure acc. to*	Rozporządzenie 2017/745 w sprawie wyrobów medycznych, załącznik IX, rozdział I, sekcja 2 i 3 oraz rozdział III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Jednostka notyfikowana / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Niemcy CE 0197
Numer rejestracyjny / *Registration number*:	HZ 1198082-1
Numer wersji / *Version number*	01
Zastępuje Deklarację zgodności z / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 Miejscowość, data / *Place, date*	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services **Kulzer GmbH** Imię i nazwisko, stanowisko / *Name and function*

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

KULZER
MITSUI CHEMICALS GROUP

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

Wyrób medyczny / *The medical device*	**Provil Novo**
Numer wersji / *Version number*	01
Zastępuje załącznik z dnia / *Replaces Annex from*	N/A
Poniższa lista artykułów obowiązuje dla następujących wersji deklaracji zgodności / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Numer wyrobu / *Article number***	**Nazwa / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
+J014660464740	66046474	Provil Novo P Reg 1x900
+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

Hanau, 01.11.2023

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*

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*	**Provil Novo**
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*	Q010201 35866 16-679 ++J0141209IMA0201eU4
da classe / *of class*	IIa
em conformidade com o regulamento / *according to rule*	5-1, 19-3 em conformidade com o Anexo VIII do Regulamento 2017/745 relativo aos Dispositivos Médicos / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Normas harmonizadas aplicadas, normas nacionais ou outros documentos normativos / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* Outras normas aplicadas, ver Documentação técnica do produto Provil Novo, Versão 1 *Further Applied standards see Technical Documentation of Provil Novo, Version 1*
Procedimento de avaliação da conformidade de acordo com / *Conformity assessment procedure acc. to*	Anexo IX do Regulamento 2017/745 relativo aos Dispositivos Médicos, Capítulo I, secção 2 e 3 e Capítulo III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organismo notificado / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Alemanha CE 0197
Número de registo / *Registration number*:	HZ 1198082-1
Número de versão / *Version number*	01
Substitui a Declaração de Conformidade de / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 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.*

KULZER
MITSUI CHEMICALS GROUP

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

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

UDI-DI / *UDI-DI*	**Número de artigo / *Article number***	**Nome / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
+J014660464740	66046474	Provil Novo P Reg 1x900
+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

Hanau, 01.11.2023

Local, data / *Place, date*

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*	**Provil Novo**
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 ++J0141209IMA0201eU4
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 Provil Novo, Versiunea 1 *Further Applied standards see Technical Documentation of Provil Novo, Version 1*
Procedură de evaluare a conformității în conf. cu / *Conformity assessment procedure acc. to*	Regulamentul privind dispozitivele medicale 2017/745, Anexa IX, Capitolul I, Secțiunile 2 și 3, și Capitolul III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Organism notificat / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Germania CE 0197
Numărul de înregistrare / *Registration number*:	HZ 1198082-1
Număr versiune / *Version number*	01
Înlocuiește Declarația de conformitate din / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 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*	**Provil Novo**
Număr versiune / *Version number*	01
Înlocuiește Anexa de la / *Replaces Annex from*	N/A
Această listă de articole este valabilă pentru declarația de conformitate versiunea / *This article list is valid for the declaration of conformity version*	01

UDI-DI / *UDI-DI*	**Număr articol / *Article number***	**Nume / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
+J014500354070	50035407	Provil Novo Med. 1x280 mL
+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
+J014660082930	66008293	Provil Novo Mono F CD 2 1x(2x50 mL)
+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
+J014660464730	66046473	Provil Novo P Fast 1 x900
+J014500354140	50035414	Provil Novo P Reg 1x500
+J014660464740	66046474	Provil Novo P Reg 1x900
+J014500354120	50035412	Provil Novo P Soft Fast 1x500
+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

Hanau, 01.11.2023

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*	**Provil Novo**
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*	Q010201 35866 16-679 ++J0141209IMA0201eU4
i klass / *of class*	IIa
enligt paragraf / *according to rule*	5-1, 19-3 enligt bilaga VIII i förordningen om medicintekniska produkter 2017/745 / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Tillämpade harmoniserade standarder, nationella standarder eller andra normerande dokument / *Applied harmonised standards, national standards or other normative documents*	EN ISO 4823 - *Dentistry – Elastomeric impression and bite registration materials* För ytterligare tillämpade standarder, se teknisk dokumentation för produkten Provil Novo, version 01 *Further Applied standards see Technical Documentation of Provil Novo, Version 01*
Förfarande för bedömning av överensstämmelse enl. / *Conformity assessment procedure acc. to*	förordning om medicintekniska 2017/745 bilaga IX, kapitel I, avsnitt 2 och 3 och kapitel III *Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*
Anmält organ / *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Tyskland CE 0197
Registreringsnummer / *Registration number*:	HZ 1198082-1
Versionsnummer / *Version number*	01
Ersätter försäkran om överensstämmelse från / *Replaces Declaration of Conformity from*	N/A
Hanau, 01.11.2023 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.*

KULZER
MITSUI CHEMICALS GROUP

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

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

UDI-DI / *UDI-DI*	**Artikelnummer / *Article number***	**Namn / *Name***
+J014660471780	66047178	Provil Novo Dynamix Putty Ref 1x(2x380 mL)
+J014500354060	50035406	Provil Novo L. 1x280 mL
+J014660464710	66046471	Provil Novo L. R CD2 1x(2x50 mL)
+J014660082900	66008290	Provil Novo L. F CD 1x(2x50 mL)
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+J014660082910	66008291	Provil Novo Med. F CD2 1x(2x50 mL)
+J014660082920	66008292	Provil Novo Med. R CD2 1x(2x50 mL)
+J014660464580	66046458	Provil Novo Mono 1x280 mL
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+J014660082940	66008294	Provil Novo Mono R CD2 1x(2x50 mL)
+J014500354150	50035415	Provil Novo P Fast 1x500
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+J014660464720	66046472	Provil Novo P Soft Fast 1x900
+J014660472030	66047203	Provil Novo P Soft Reg 1x900 mL
+J014500354110	50035411	Provil Novo P Soft Reg 1x500

i.V.

Hanau, 01.11.2023

Ort, datum / *Place, date*

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

Namn och funktion / *Name and function*