

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

Oxasil

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
 ++J0141209IMC0201pVL

der Klasse / of class

Ila

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 C-Silikone -Activator Universal Plus, Optosil,
 Oxasil, Xantopren / Further Applied standards see Technical
 Documentation of C-Silikone – Activator Universal Plus. Optosil,
 Oxasil, Xantopren, 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

13.12.2023

Hanau,

i.V.

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

30.10.2025

Ort, Datum / Place, date

Name und Funktion / Name and function

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

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

| | |
|--|---------------|
| das Medizinprodukt / <i>for the medical device</i> | Oxasil |
| Versionsnummer Artikelliste / <i>Version number article list</i> | 03 |
| Ersetzt Artikelliste vom / <i>Replaces article list from</i> | 05.02.2024 |
| Diese Artikelliste ist gültig für die Konformitätserklärung Version / <i>This article list is valid for the declaration of conformity version</i> | 02 |

| UDI-DI / UDI-DI | Artikelnummer / Article number | Name / Name |
|----------------------------|---|---------------------------------|
| +J014660773930 | 66077393 | Oxasil Very Light Flow 1x140 mL |
| +J014660773900 | 66077390 | Oxasil Soft Putty 1x900 mL |
| +J014660773910 | 66077391 | Oxasil Putty 1x900 mL |
| +J014660773940 | 66077394 | Oxasil Mucosa 1x140mL |
| +J014660773920 | 66077392 | Oxasil Light Flow 1x140 mL |
| +J014660773960 | 66077396 | Oxasil Activator Paste 60 mL |

Hanau,
30.10.2025

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 companyKulzer 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

OxasilНаименование, 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 itemsСписък с артикули, вижте Приложението /
List of Articles see Annex

Код по EMDN / EMDN-Code

Q010201

Код по GMDN / GMDN code

35866

Код по UMDNS / UMDNS code

16-679

Основна UDI-DI идентификация / Basic UDI-DI

++J0141209IMC0201pVL

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 documentsEN ISO 4823 Dentistry – Elastomeric impression and bite
registration materialsДруги приложени стандарти, вижте техническата
документация на продукт C-Silikone – Activator Universal Plus,
Optosil, Oxasil, Xantopren Версия 02
Further Applied standards see Technical Documentation of C-
Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren,
Version 02Процедура за оценка на съответствието съгласно /
Conformity assessment procedure acc. toРегламента 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

13.12.2023

Ханану,

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

30.10.2025

Място, дата / Place, date

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 / **Oxasil**
The medical device

Номер на версия / *Version number* 03

Заменя Приложението от / *Replaces Annex from* 05.02.2024

Този списък със статии е валиден във връзка с *02*
декларацията за съответствие, версия / *This*
This article list is valid for the declaration of
conformity version

| UDI-DI / UDI-DI | Номер на артикул / Article number | Наименование / Name |
|------------------------|--|---------------------------------|
| +J014660773930 | 66077393 | Oxasil Very Light Flow 1x140 mL |
| +J014660773900 | 66077390 | Oxasil Soft Putty 1x900 mL |
| +J014660773910 | 66077391 | Oxasil Putty 1x900 mL |
| +J014660773940 | 66077394 | Oxasil Mucosa 1x140mL |
| +J014660773920 | 66077392 | Oxasil Light Flow 1x140 mL |
| +J014660773960 | 66077396 | Oxasil Activator Paste 60 mL |

Ханау,
30.10.2025

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* **Oxasil**

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
 ++J0141209IMC0201pVL

třídy / *of class*

Ila

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 C-Silikone - Activator Universal Plus, Optosil, Oxasil,
 Xantopren, verze 02 / *Further Applied standards see Technical*
Documentation of C-Silikone - Activator Universal Plus, Optosil,
Oxasil, Xantopren, 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

13.12.2023

Hanau,

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

30.10.2025

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.



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

Zdravotnický prostředek / *The medical device* **Oxasil**

Číslo verze / *Version number* 03

Nahrazuje přílohu ze dne / *Replaces Annex from* 05.02.2024

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 |
|------------------------|---|---------------------------------|
| +J014660773930 | 66077393 | Oxasil Very Light Flow 1x140 mL |
| +J014660773900 | 66077390 | Oxasil Soft Putty 1x900 mL |
| +J014660773910 | 66077391 | Oxasil Putty 1x900 mL |
| +J014660773940 | 66077394 | Oxasil Mucosa 1x140mL |
| +J014660773920 | 66077392 | Oxasil Light Flow 1x140 mL |
| +J014660773960 | 66077396 | Oxasil Activator Paste 60 mL |

Hanau,
30.10.2025

Místo, datum / *Place, date*

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

Jméno a funkce / *Name and function*

**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

OxasilΕπωνυμία, 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-DIQ010201
35866
16-679
++J0141209IMC0201pVL

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 documentsEN ISO 4823 Dentistry – Elastomeric impression and bite
registration materials
Για περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική
τεκμηρίωση του Προϊόντος C-Silikone - Activator Universal Plus,
Optosil, Oxasil, Xantopren, έκδοση 02 / Further Applied standards
see Technical Documentation of C-Silikone - Activator Universal
Plus, Optosil, Oxasil, Xantopren, Version 02Διαδικασία αξιολόγησης συμμόρφωσης σύμφωνα με /
Conformity assessment procedure acc. toΚανονισμός 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

13.12.2023

Hanau,
30.10.2025i.V. Dr. Matthias Hartmann 
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbHΤόπος, ημερομηνία / Place,
date

Όνοματεπώνυμο 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* **Oxasil**

Αριθμός έκδοσης / *Version number* 03

Αντικαθιστά το Παράρτημα από / *Replaces Annex from* 05.02.2024

Αυτός ο κατάλογος προϊόντων ισχύει για την έκδοση δήλωσης συμμόρφωσης / *This article list is valid for the declaration of conformity version* 02

| UDI-DI / <i>UDI-DI</i> | Αριθμός είδους / <i>Article number</i> | Όνομα / <i>Name</i> |
|------------------------|--|---------------------------------|
| +J014660773930 | 66077393 | Oxasil Very Light Flow 1x140 mL |
| +J014660773900 | 66077390 | Oxasil Soft Putty 1x900 mL |
| +J014660773910 | 66077391 | Oxasil Putty 1x900 mL |
| +J014660773940 | 66077394 | Oxasil Mucosa 1x140mL |
| +J014660773920 | 66077392 | Oxasil Light Flow 1x140 mL |
| +J014660773960 | 66077396 | Oxasil Activator Paste 60 mL |

Hanau,
30.10.2025

Τόπος, ημερομηνία / *Place, date*

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

Όνοματεπώνυμο και τίτλος / *Name and function*

IZJAVA O USKLAĐENOSTI / *DECLARATION OF CONFORMITY*

Naziv i adresa tvrtke /
Name and address of the company

Kulzer GmbH
 Leipziger Straße 2, 63450 Hanau
 Njemačka / Germany
 SRN: DE-MF-00007705

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

medicinski proizvod / *the medical device*

Oxasil

Naziv, tip ili model, broj serije, po mogućnosti izvori i broj stavki / *Name, type or model, batch or serial number, possibly sources and number of items*

Popis artikala, pogledajte Dodatak / *List of Articles see Annex*

šifra EMDN / *EMDN-Code*

Q010201

šifra GMDN / *GMDN code*

35866

šifra UMDNS / *UMDNS code*

16-679

osnovni UDI-DI / *Basic UDI-DI*

++J0141209IMC0201pVL

klase / *of class*

Ila

u skladu s pravilom / *according to rule*

5-1, 19-3 u skladu s Dodatkom VIII Uredbe 2017/745 o medicinskim proizvodima / *according to Annex VIII of Medical Device Regulation 2017/745*

ispunjava sve odredbe Uredbe 2017/745 o medicinskim proizvodima koje se na njega odnose. / *meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.*

Primijenjene usklađene norme, državne norme ili drugi normativni dokumenti / *Applied harmonised standards, national standards or other normative documents*

EN ISO 4823 *Dentistry – Elastomeric impression and bite registration materials*

Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, verzija 02 / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 02*

Postupak procjene usklađenosti prema / *Conformity assessment procedure acc. to*

Prilog IX Uredbi 2017/745 o medicinskim proizvodima, Poglavlje I, Odjeljak 2 i 3 te Poglavlje III
Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III

Obaviješteno tijelo / *Notified Body*

TÜV Rheinland LGA Products GmbH
 Tillystrasse 2
 90431 Nürnberg / Njemačka

CE 0197

Registracijski broj / *Registration number:*

HZ 1198082-1

Broj verzije / *Version number*

02

Zamjenjuje Izjavu o usklađenosti od / *Replaces Declaration of Conformity from*

13.12.2023

Hanau,

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

30.10.2025

Mjesto, datum / *Place, date*

Ime i funkcija / *Name and function*

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



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

Medicinski proizvod / **Oxasil**
The medical device

Broj verzije / *Version number* 03

Zamjenjuje Dodatak od / 05.02.2024
Replaces Annex from

Ovaj popis artikala valjan je za verziju izjave 02
u sukladnosti / *This article list is valid for the*
declaration of conformity version

| UDI-DI / UDI-DI | Broj artikla / Article number | Naziv / Name |
|------------------------|--------------------------------------|---------------------------------|
| +J014660773930 | 66077393 | Oxasil Very Light Flow 1x140 mL |
| +J014660773900 | 66077390 | Oxasil Soft Putty 1x900 mL |
| +J014660773910 | 66077391 | Oxasil Putty 1x900 mL |
| +J014660773940 | 66077394 | Oxasil Mucosa 1x140mL |
| +J014660773920 | 66077392 | Oxasil Light Flow 1x140 mL |
| +J014660773960 | 66077396 | Oxasil Activator Paste 60 mL |

Hanau,
30.10.2025

Mjesto, datum / *Place, date*

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

Ime i funkcija / *Name and function*

**MEGFELELŐSÉGI NYILATKOZAT / DECLARATION OF CONFORMITY**A vállalat neve és címe /
Name and address of the company**Kulzer GmbH**
Leipziger Straße 2, 63450 Hanau
Németország / Germany
SRN: DE-MF-000007705Kizárólagos felelősségünkre kijelentjük, hogy / We declare under our sole responsibility that
az orvostechikai eszköz / the medical device **Oxasil**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-DIQ010201
35866
16-679
++J0141209IMC0201pVL

osztálya / of class

IIa

a következő szabály szerint / according to rule

5-1, 19-3 az orvostechikai eszközökről szóló 2017/745 rendelet VIII.
melléklete szerint / according to Annex VIII of Medical Device
Regulation 2017/745**megfelel az orvostechikai 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 documentsEN ISO 4823 Dentistry – Elastomeric impression and bite registration
materials
További alkalmazott szabványokat lásd a műszaki dokumentációban,
termék: C-Szilikon - Activator Universal Plus, Optosil, Oxasil,
Xantopren, 02. verzió / Further Applied standards see Technical
Documentation of C-Szilikon - Activator Universal Plus, Optosil, Oxasil,
Xantopren, Version 02Megfelelőségértékelési eljárás a következő szerint
/ Conformity assessment procedure acc. toAz orvostechikai 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

13.12.2023

Hanau,
30.10.2025i.V. Dr. Matthias Hartmann
Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Hely, dátum / Place, date

Név és funkció / Name and function

Ez a megfelelőségi nyilatkozat 2 évig érvényes a gyártott eszközök adott tételére vonatkozó kibocsátási dokumentumokkal együtt. / This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.



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

Az orvostechnikai eszköz / *The medical device* **Oxasil**

Verziószám / *Version number* 03

Felváltja a mellékletet ettől / *Replaces Annex from* 05.02.2024

Ez a tételista 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 |
|------------------------|--------------------------------------|---------------------------------|
| +J014660773930 | 66077393 | Oxasil Very Light Flow 1x140 mL |
| +J014660773900 | 66077390 | Oxasil Soft Putty 1x900 mL |
| +J014660773910 | 66077391 | Oxasil Putty 1x900 mL |
| +J014660773940 | 66077394 | Oxasil Mucosa 1x140mL |
| +J014660773920 | 66077392 | Oxasil Light Flow 1x140 mL |
| +J014660773960 | 66077396 | Oxasil Activator Paste 60 mL |

Hanau,
30.10.2025

Hely, dátum / *Place, date*

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

Név és funkció / *Name and function*

DEKLARACJA ZGODNOŚCI / DECLARATION OF CONFORMITY

| | |
|--|--|
| Nazwa i adres firmy / <i>Name and address of the company</i> | 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 / <i>the medical device</i> | Oxasil |
| Nazwa, typ lub model, numer partii lub serii, ewentualnie źródła i liczba elementów / <i>Name, type or model, batch or serial number, possibly sources and number of items</i> | Wykaz wyrobów znajduje się w załączniku / <i>List of Articles see Annex</i> |
| Kod wyrobu wg EMDN / <i>EMDN-Code</i> | Q010201 |
| Kod wyrobu wg GMDN / <i>GMDN code</i> | 35866 |
| Kod wyrobu wg UMDNS / <i>UMDNS code</i> | 16-679 |
| Kod Basic UDI-DI / <i>Basic UDI-DI</i> | ++J0141209IMC0201pVL |
| klasy / <i>of class</i> | Ila |
| zgodnie z regułą / <i>according to rule</i> | 5-1, 19-3 zgodnie z załącznikiem VIII do Rozporządzenia 2017/745 w sprawie wyrobów medycznych / <i>according to Annex VIII of Medical Device Regulation 2017/745</i> |
| spełnia wszystkie przepisy Rozporządzenia 2017/745 w sprawie wyrobów medycznych, które go dotyczą. / <i>meets all the provisions of the Medical Device Regulation 2017/745 which apply to it.</i> | |
| Zastosowane normy zharmonizowane, normy krajowe lub inne dokumenty normatywne / <i>Applied harmonised standards, national standards or other normative documents</i> | EN ISO 4823 <i>Dentistry – Elastomeric impression and bite registration materials</i> Pozostałe stosowane normy znajdują się w dokumentacji technicznej produktu C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, wersja 02 / <i>Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 02</i> |
| Procedura oceny zgodności wg. / <i>Conformity assessment procedure acc. to</i> | Rozporządzenie 2017/745 w sprawie wyrobów medycznych, załącznik IX, rozdział I, sekcja 2 i 3 oraz rozdział III <i>Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III</i> |
| Jednostka notyfikowana / <i>Notified Body</i> | TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg/Niemcy CE 0197 |
| Numer rejestracyjny / <i>Registration number:</i> | HZ 1198082-1 |
| Numer wersji / <i>Version number</i> | 02 |
| Zastępuje Deklarację zgodności z / <i>Replaces Declaration of Conformity from</i> | 13.12.2023 |
| Hanau, 30.10.2025 | i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services Kulzer GmbH |
| Miejscowość, data / <i>Place, date</i> | Imię i nazwisko, stanowisko / <i>Name and function</i> |



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.*

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

Wyrób medyczny / *The medical device* **Oxasil**

Numer wersji / *Version number* 03

Zastępuje załącznik z dnia / *Replaces Annex from* 05.02.2024

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 |
|------------------------|--------------------------------------|---------------------------------|
| +J014660773930 | 66077393 | Oxasil Very Light Flow 1x140 mL |
| +J014660773900 | 66077390 | Oxasil Soft Putty 1x900 mL |
| +J014660773910 | 66077391 | Oxasil Putty 1x900 mL |
| +J014660773940 | 66077394 | Oxasil Mucosa 1x140mL |
| +J014660773920 | 66077392 | Oxasil Light Flow 1x140 mL |
| +J014660773960 | 66077396 | Oxasil Activator Paste 60 mL |

Hanau,
30.10.2025

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-00007705

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

dispozitivul medical / *the medical device*

Oxasil

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*

Q010201

Cod GMDN / *GMDN code*

35866

Cod UMDNS / *UMDNS code*

16-679

UDI-DI de bază / *Basic UDI-DI*

++J0141209IMC0201pVL

din clasa / *of class*

Ila

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 C-
 Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren,
 Versiunea 02 / *Further Applied standards see Technical
 Documentation of C-Silikone - Activator Universal Plus, Optosil,
 Oxasil, Xantopren, 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 / Germany

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

13.12.2023

Hanau,

i.V.

30.10.2025

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

Loc, dată / *Place, date*

Nume și funcție / *Name and function*

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

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

Dispozitivul medical / **Oxasil**
The medical device

Număr versiune / *Version number* 03

Înlocuiește Anexa de la / *Replaces Annex from* 05.02.2024

Această listă de articole este valabilă pentru *02*
declarația de conformitate versiunea / *This*
article list is valid for the declaration of
conformity version

| UDI-DI / UDI-DI | Număr articol / Article number | Nume / Name |
|------------------------|---------------------------------------|---------------------------------|
| +J014660773930 | 66077393 | Oxasil Very Light Flow 1x140 mL |
| +J014660773900 | 66077390 | Oxasil Soft Putty 1x900 mL |
| +J014660773910 | 66077391 | Oxasil Putty 1x900 mL |
| +J014660773940 | 66077394 | Oxasil Mucosa 1x140mL |
| +J014660773920 | 66077392 | Oxasil Light Flow 1x140 mL |
| +J014660773960 | 66077396 | Oxasil Activator Paste 60 mL |

Hanau,
30.10.2025
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-00007705

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

medicinski pripomoček / the medical device

Oxasil

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
 ++J0141209IMC0201pVL

razreda / of class

Ila

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 C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, različica 02 / Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, Version 02

Postopek ugotavljanja skladnosti v skladu s /
 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

13.12.2023

Hanau,
 30.10.2025

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

Kraj, datum / Place, date

Ime in položaj / Name and function

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



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

Medicinski pripomoček / **Oxasil**
The medical device

Številka različice / *Version number* 03

Nadomešča Prilogo z dne / 05.02.2024
Replaces Annex from

Ta seznam izdelkov velja za naslednjo 02
različico izjave o skladnosti / This article list is
valid for the declaration of conformity version

| UDI-DI / UDI-DI | Številka artikla / Article number | Ime / Name |
|-----------------|--------------------------------------|---------------------------------|
| +J014660773930 | 66077393 | Oxasil Very Light Flow 1x140 mL |
| +J014660773900 | 66077390 | Oxasil Soft Putty 1x900 mL |
| +J014660773910 | 66077391 | Oxasil Putty 1x900 mL |
| +J014660773940 | 66077394 | Oxasil Mucosa 1x140mL |
| +J014660773920 | 66077392 | Oxasil Light Flow 1x140 mL |
| +J014660773960 | 66077396 | Oxasil Activator Paste 60 mL |

Hanau,
30.10.2025

Kraj, datum / *Place, date*

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-00007705

Vyhlasujeme na svoju výlučnú zodpovednosť, že / *We declare under our sole responsibility that*
 zdravotnícka pomôcka / *the medical device* **Oxasil**

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* Q010201
 Kód GMDN / *GMDN code* 35866
 Kód UMDNS / *UMDNS code* 16-679
 Základné identifikačné číslo UDI-DI / *Basic UDI-DI* ++J0141209IMC0201pVL

triedy / *of class* IIa

podľa pravidiel / *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.*

Použitie 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 C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren / *Further Applied standards see Technical Documentation of C-Silikone - Activator Universal Plus, Optosil, Oxasil, Xantopren, 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* 13.12.2023

Hanau, i.V.
 30.10.2025 Dr. Matthias Hartmann 
 Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Miesto, dátum / *Place, date* Meno a funkcia / *Name and function*

Toto vyhlásenie o zhode je platné 2 roky v súvislosti s dokumentmi o uvoľnení príslušnej šarže vyrobených pomôcok. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.*



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

Zdravotnícka pomôcka / **Oxasil**
The medical device

Číslo verzie / *Version number* 03

Nahrádza prílohu z / 05.02.2024
Replaces Annex from

Tento zoznam tovaru je platný pre vyhlásenie 02
o zhode, verzia / *This article list is valid for*
the declaration of conformity version

| UDI-DI / <i>UDI-DI</i> | Číslo položky / <i>Article number</i> | Meno / <i>Name</i> |
|------------------------|---------------------------------------|---------------------------------|
| +J014660773930 | 66077393 | Oxasil Very Light Flow 1x140 mL |
| +J014660773900 | 66077390 | Oxasil Soft Putty 1x900 mL |
| +J014660773910 | 66077391 | Oxasil Putty 1x900 mL |
| +J014660773940 | 66077394 | Oxasil Mucosa 1x140mL |
| +J014660773920 | 66077392 | Oxasil Light Flow 1x140 mL |
| +J014660773960 | 66077396 | Oxasil Activator Paste 60 mL |

Hanau,
30.10.2025

Miesto, dátum / *Place, date*

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

Meno a funkcia / *Name and function*