

## 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

**Heraenium – Nichtedelmetall-Legierungen / Heraenium – Non-precious metal alloys**

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

Q010601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

der Klasse / of class

Ila

nach Regel / according to rule

8-1 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 22674 Zahnheilkunde - Metallische Werkstoffe für  
 festsitzenden und herausnehmbaren Zahnersatz und Applikationen  
 / Dentistry - Metallic materials for fixed and removable restorations  
 and appliances  
 Weitere angewandte Normen siehe Version 02 der Technischen  
 Dokumentation von Produkt Non-precious metal alloys / Further  
 Applied standards see Technical Documentation of Product Non-  
 precious metal alloys, 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

20.09.2023

Hanau, 10.09.2025

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

Ort, Datum / Place, date

Name und Funktion / Name and function

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

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

das Medizinprodukt /  
for the medical device

**Heraenium – Nichtedelmetall-  
Legierungen / Heraenium – Non-  
precious metal alloys**

Versionsnummer Artikelliste /  
Version number article list

03


Ersetzt Artikelliste vom /  
Replaces article list from

10.09.2025

Diese Artikelliste ist gültig für die Konformitätserklärung Version / 02  
This article list is valid for the declaration of conformity version

<b>UDI-DI / UDI-DI</b>	<b>Artikelnummer / Article number</b>	<b>Name / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

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

Ort, Datum / Place, date

Name und Funktion / Name and function

## ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ / DECLARATION OF CONFORMITY

Име и адрес на фирмата /  
 Name and address of the company

**Kulzer GmbH**  
 Leipziger Straße 2, 63450 Hanau  
 Германия / Germany

SRN: DE-MF-000007705

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

медицинското изделие / the medical device

**Heraenium – Non-Precious Metal Alloys**

Наименование, тип или модел, партиден или  
 сериен номер, евентуално произход и брой  
 елементи / Name, type or model, batch or serial  
 number, possibly sources and number of items

Списък с артикули, вижте Приложението /  
 List of Articles see Annex

Код по EMDN / EMDN-Code  
 Код по GMDN / GMDN code  
 Код по UMDNS / UMDNS code  
 Основна UDI-DI идентификация / Basic UDI-DI

Q010601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

от клас / of class

IIa

съгласно правило / according to rule

8-1 съгласно Приложение VIII от Регламента за медицинските  
 изделия 2017/745 / according to Annex VIII of Medical Device  
 Regulation 2017/745

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

Приложени хармонизирани стандарти,  
 национални стандарти или други нормативни  
 документи / Applied harmonised standards,  
 national standards or other normative documents

EN ISO 22674 Dentistry – Metallic materials for fixed and  
 removable restorations and appliances

Други приложени стандарти, вижте техническата документация  
 на продукт Non-Precious Metal Alloys, Версия 02 / Further  
 applied standards see Technical Documentation of Product Non-  
 Precious Metal Alloys, Version 02

Процедура за оценка на съответствието  
 съгласно /  
 Conformity assessment procedure acc. to

Регламента за медицинските изделия 2017/745 Приложение IX,  
 глава I, раздел 2 и 3 и глава III  
 Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2  
 and 3 and Chapter III

Нотифициран орган / Notified Body

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Германия

CE 0197

Регистрационен номер / Registration number:

HZ 1198082-1

Номер на версия / Version number

02

Заменя Декларация за съответствие от /  
 Replaces Declaration of Conformity from

20.09.2023

Ханану, 06.02.2026



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

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 / *The medical device* **Heraenium - Non-Precious Metal Alloys**

Номер на версия / *Version number* 03

Заменя Приложението от / *Replaces Annex from* 06.02.2026

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

<b>UDI-DI / UDI-DI</b>	<b>Номер на артикул / Article number</b>	<b>Наименование / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Ханау, 11.02.2026

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

**Heraenium – Non-Precious Metal Alloys**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 itemsSeznam položek je uveden v příloze /  
List of Articles see Annex

Kód EMDN / EMDN-Code

Q010601

Kód GMDN / GMDN code

35857

Kód UMDNS / UMDNS code

16-661

Základní UDI-DI / Basic UDI-DI

++J0141103NPMA0601aGJ

třídy / of class

IIa

podle pravidla / according to rule

8-1 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  
documentsEN ISO 22674 Dentistry – Metallic materials for fixed and  
removable restorations and appliancesDalší použité normy najdete v technické dokumentaci k výrobku  
Non-Precious Metal Alloys, verze 02 / Further applied standards  
see Technical Documentation of Product Non-Precious Metal  
Alloys, Version 02Procedura posouzení shody podle /  
Conformity assessment procedure acc. tonařízení 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

20.09.2023

Hanau, 06.02.2026

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.

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

Zdravotnický prostředek /  
 The medical device

**Heraenium - Non-Precious Metal Alloys**

Číslo verze / Version number

03

Nahrazuje přílohu ze dne /  
 Replaces Annex from

06.02.2026

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
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

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, 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

**Heraenium – Non-Precious Metal Alloys**

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

Q010601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

i klasse / of class

IIa

i henhold til artikel / according to rule

8-1 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 22674 Dentistry – Metallic materials for fixed and  
 removable restorations and appliances

Andre anvendte standarder kan ses i det tekniske  
 dokumentationsmateriale til produktet Non-Precious Metal Alloys,  
 version 02 / Applied standards see Technical Documentation of  
 Product Non-Precious Metal Alloys, Version 02

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  
 90431 Nürnberg / Tyskland

CE 0197

Registreringsnummer / Registration number:

HZ 1198082-1

Versionsnummer / Version number

02

Erstatter overensstemmelseserklæring fra /  
 Replaces Declaration of Conformity from

20.09.2023

Hanau, 06.02.2026

  
 på vegne af Dr. Matthias Hartmann  
 Head of Global Quality, Regulatory & Scientific Services  
**Kulzer GmbH**

Sted, dato / Place, date

Navn og stilling / Name and function

Denne konformitetserklæring gælder i 2 år i forbindelse med frigivelsesdokumenterne for det aktuelle parti af produceret medicinsk udstyr. / This statement of conformity is valid for 2 years in connection with the release documents for the respective batch of produced devices.

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

Det medicinske udstyr / *The medical device* **Heraenium - Non-Precious Metal Alloys**

Versionsnummer / *Version number* 03

Erstatter bilag fra / *Replaces Annex from* 06.02.2026

Denne artikelliste er gyldig i forbindelse med overensstemmelseserklæringen version / *This article list is valid for the declaration of conformity version* 02

<b>UDI-DI / UDI-DI</b>	<b>Varenummer / Article number</b>	<b>Betegnelse / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

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*

## 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

**Heraenium – Non-Precious Metal Alloys**

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

Q010601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

de la clase / of class

Ila

de acuerdo con la norma / according to rule

8-1 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 22674 Dentistry – Metallic materials for fixed and  
 removable restorations and appliance

Para otras normas aplicadas consulte la documentación técnica del  
 producto Non-Precious Metal Alloys, versión 02 / Further applied  
 standards see Technical Documentation of Product Non-Precious  
 Metal Alloys, Version 02

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 / Saksamaa

CE 0197

Número de registro / Registration number:

HZ 1198082-1

Número de versión / Version number

02

Sustituye a la declaración de conformidad del /  
 Replaces Declaration of Conformity from

20.09.2023



Hanau, 06.02.2026

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

Lugar, fecha / Place, date

Nombre y cargo / Name and function

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

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

El producto sanitario / *The medical device* **Heraenium - Non-Precious Metal Alloys**

Número de versión / *Version number* 03

Sustituye al Anexo del / *Replaces Annex from* 06.02.2026

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* 02

<b>UDI-DI / UDI-DI</b>	<b>Número de artículo / Article number</b>	<b>Nombre / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

Lugar, fecha / *Place, date*



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

Nombre y cargo / *Name and function*



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

Le dispositif médical / *The medical device* **Heraenium – Non-precious metal alloys**

Numéro de version / *Version number* 03

Remplace l'annexe de / *Replaces Annex from* 10.09.2025

Cette liste d'articles est valable pour la déclaration de conformité, version / *This article list is valid for the declaration of conformity version* 02

<b>UDI-DI / UDI-DI</b>	<b>Numéro de référence / Article number</b>	<b>Nom / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

Lieu, date / *Place, date*



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

Nom et fonction / *Name and function*

**ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ / DECLARATION OF CONFORMITY**Επωνυμία και διεύθυνση εταιρείας /  
Name and address of the company**Kulzer GmbH**  
Leipziger Straße 2, 63450 Hanau  
Γερμανία / Germany  
SRN: DE-MF-000007705**Δηλώνουμε με δική μας ευθύνη ότι / We declare under our sole responsibility that**

το ιατροτεχνολογικό προϊόν / the medical device

**Heraenium – Non-Precious Metal Alloys**Επωνυμία, τύπος ή μοντέλο, παρτίδα ή αριθμός  
σειράς, πιθανές πηγές και αριθμός ειδών / Name,  
type or model, batch or serial number, possibly  
sources and number of items

Κατάλογος ειδών Παράρτημα / List of Articles see Annex

Κωδικός EMDN / EMDN-Code  
Κωδικός GMDN / GMDN code  
Κωδικός UMDNS / UMDNS code  
Βασικό UDI-DI / Basic UDI-DIQ010601  
35857  
16-661  
++J0141103NPMA0601aGJ

κλάση / of class

IIa

σύμφωνα με τον κανόνα / according to rule

8-1 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 22674 Dentistry – Metallic materials for fixed and  
removable restorations and appliancesΓια περαιτέρω εφαρμοζόμενα πρότυπα βλ. την τεχνική τεκμηρίωση  
του προϊόντος Non-Precious Metal Alloys, έκδοση 02 / Further  
applied standards see Technical Documentation of Product Non-  
Precious Metal Alloys, 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

20.09.2023

Hanau, 06.02.2026

i.V. Dr. Matthias Hartmann  
Head of Global Quality, Regulatory & Scientific Services  
**Kulzer GmbH**Τόπος, 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* **Heraenium - Non-Precious Metal Alloys**

Αριθμός έκδοσης / *Version number* 03

Αντικαθιστά το Παράρτημα από / *Replaces Annex from* 06.02.2026

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

<b>UDI-DI / UDI-DI</b>	<b>Αριθμός είδους / Article number</b>	<b>Όνομα / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026


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 / <i>Name and address of the company</i>	<b>Kulzer GmbH</b> Leipziger Straße 2, 63450 Hanau Njemačka / Germany SRN: DE-MF-000007705
<b>Izjavljujemo pod punom odgovornošću da / We declare under our sole responsibility that</b>	
medicinski proizvod / <i>the medical device</i>	<b>Heraenium – Non-Precious Metal Alloys</b>
Naziv, tip ili model, broj serije, po mogućnosti izvori i broj stavki / <i>Name, type or model, batch or serial number, possibly sources and number of items</i>	Popis artikala, pogledajte Dodatak / <i>List of Articles see Annex</i>
šifra EMDN / <i>EMDN-Code</i>	Q010601
šifra GMDN / <i>GMDN code</i>	35857
šifra UMDNS / <i>UMDNS code</i>	16-661
osnovni UDI-DI / <i>Basic UDI-DI</i>	++J0141103NPMA0601aGJ
klase / <i>of class</i>	IIa
u skladu s pravilom / <i>according to rule</i>	8-1 u skladu s Dodatkom VIII Uredbe 2017/745 o medicinskim proizvodima / <i>according to Annex VIII of Medical Device Regulation 2017/745</i>
<b>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.</b>	
Primijenjene usklađene norme, državne norme ili drugi normativni dokumenti / <i>Applied harmonised standards, national standards or other normative documents</i>	EN ISO 22674 Dentistry – Metallic materials for fixed and removable restorations and appliances  Druge primijenjene norme, pogledajte Tehničku dokumentaciju za proizvod Non-Precious Metal Alloys , verzija 02 / <i>Further applied standards see Technical Documentation of Product Non-Precious Metal Alloys, Version 02</i>
Postupak procjene usklađenosti prema / <i>Conformity assessment procedure acc. to</i>	Prilog IX Uredbi 2017/745 o medicinskim proizvodima, Poglavlje I, Odjeljak 2 i 3 te Poglavlje III  <i>Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III</i>
Obaviješteno tijelo / <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg / Njemačka  CE 0197
Registracijski broj / <i>Registration number</i> :	HZ 1198082-1
Broj verzije / <i>Version number</i>	02
Zamjenjuje Izjavu o usklađenosti od / <i>Replaces Declaration of Conformity from</i>	20.09.2023  
Hanau, 06.02.2026	i.V. Dr. Matthias Hartmann Head of Global Quality, Regulatory & Scientific Services <b>Kulzer GmbH</b>
Mjesto, datum / <i>Place, date</i>	Ime i funkcija / <i>Name and function</i>

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 / <i>The medical device</i>	<b>Heraenium - Non-Precious Metal Alloys</b>
Broj verzije / <i>Version number</i>	03
Zamjenjuje Dodatak od / <i>Replaces Annex from</i>	06.02.2026
Ovaj popis artikala valjan je za verziju izjave u sukladnosti / <i>This article list is valid for the declaration of conformity version</i>	02

<b>UDI-DI / UDI-DI</b>	<b>Broj artikla / Article number</b>	<b>Naziv / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

Mjesto, datum / *Place, date*



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

Ime i funkcija / *Name and function*

## MEGFELELŐSÉGI NYILATKOZAT / DECLARATION OF CONFORMITY

A vállalat neve és címe /  
 Name and address of the company

**Kulzer GmbH**  
 Leipziger Straße 2, 63450 Hanau  
 Németország / Germany  
 SRN: DE-MF-000007705

**Kizárólagos felelősségünkre kijelentjük, hogy / We declare under our sole responsibility that**  
 az orvostechikai eszköz / the medical device **Heraenium – Non-precious metal alloys**

Név, típus vagy modell, tétel vagy sorozatszám,  
 esetleg források és tételek száma / Name, type or  
 model, batch or serial number, possibly sources and  
 number of items

A cikkek listáját lásd a mellékletben / List of Articles see Annex

EMDN kód / EMDN-Code  
 GMDN kód / GMDN code  
 UMDNS kód / UMDNS code  
 Alapvető UDI-DI / Basic UDI-DI

Q10601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

osztálya / of class

Ila

a következő szabály szerint / according to rule

8-1 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 documents

EN ISO 22674 Dentistry - Metallic materials for fixed and removable  
 restorations and appliances  
 További alkalmazott szabványokat lásd a műszaki dokumentációban,  
 termék: Non-precious metal alloys, 02. verzió  
 Further Applied standards see Technical Documentation of  
 Product Non-precious metal alloys, Version 02

Megfelelőségértékelési eljárás a következő szerint /  
 Conformity assessment procedure acc. to

Az 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

20.09.2023

Hanau, 10.09.2025

i.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: Megfeleléségi nyilatkozat / Declaration of Conformity**

Az orvostechikai eszköz / The medical device	<b>Heraenium – Non-precious metal alloys</b>
Verziószám / Version number	03
Felváltja a mellékletet ettől / Replaces Annex from	10.09.2025
Ez a tételista a megfeleléségi 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
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

Hely, dátum / Place, date



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

---

 Név és funkció / 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*

**Heraenium – Non-precious metal alloys**

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*

Q10601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

di classe / *of class*

Ila

secondo la norma / *according to rule*

8-1 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 22674 Dentistry - Metallic materials for fixed and  
 removable restorations and appliances  
 Ulteriori norme applicate vedi Documentazione tecnica di  
 Prodotto Non-precious metal alloys, Versione 02  
*Further Applied standards see Technical Documentation of  
 Product Non-precious metal alloys, Version 02*

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*

02

Sostituisce la dichiarazione di conformità di /  
*Replaces Declaration of Conformity from*

20.09.2023

Hanau, 10.09.2025

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

Luogo, data / *Place, date*

Nome e funzione / *Name and function*

La presente dichiarazione di conformità ha validità di 2 anni in relazione ai documenti di rilascio per il lotto corrispondente di  
 dispositivi prodotti. / *This statement of conformity is valid for 2 years in connection with the release documents for the respective  
 batch of produced devices.*

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

Il dispositivo medico / *The medical device* **Heraenium – Non-precious metal alloys**

Numero versione / *Version number* 03

Sostituisce l'allegato da / *Replaces Annex from* 10.09.2025

Questa lista di articoli è valida per la versione 02  
 della dichiarazione di conformità / *This article  
 list is valid for the declaration of conformity  
 version*

<b>UDI-DI / UDI-DI</b>	<b>Numero articolo / Article number</b>	<b>Nome / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

Luogo, data / *Place, date*



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

Nome e funzione / *Name and function*

## ATITIKTIES DEKLARACIJA / DECLARATION OF CONFORMITY

Bendrovės pavadinimas ir adresas /  
*Name and address of the company*

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

**Prisiimdami visą atsakomybę pareiškiame, kad / We declare under our sole responsibility that**  
 medicinos prietaisais / *the medical device* **Heraenium – Non-precious metal alloys**

Pavadinimas, tipas arba modelis, partija arba serijos numeris, galimi šaltiniai ir elementų skaičius / *Name, type or model, batch or serial number, possibly sources and number of items*

Prekių sąrašo ieškokite Priede / *List of Articles see Annex*

EMDN kodas / *EMDN-Code*  
 GMDN kodas / *GMDN code*  
 UMDNS kodas / *UMDNS code*  
 Pagrindinis UDI-DI / *Basic UDI-DI*

Q10601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

klasės / *of class*

Ila

pagal taisyklę / *according to rule*

8-1 Pagal Medicinos prietaisų reglamento 2017/745 VIII priedą / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Taikomi harmonizuotieji standartai, nacionaliniai standartai ar kiti normatyviniai dokumentai / *Applied harmonised standards, national standards or other normative documents*

EN ISO 22674 Dentistry - Metallic materials for fixed and removable restorations and appliances atkuriamosiomis medžiagomis Kitus taikomus standartus žr. produkto Non-precious metal alloys, techninėje dokumentacijoje, 02 versijoje  
*Further Applied standards see Technical Documentation of Product Non-precious metal alloys, Version 02*

Atitikties patvirtinimo procedūra pagal /  
*Conformity assessment procedure acc. to*

Medicinos priemonių reglamento 2017/745 IX priedas, I skyrius, 2 ir 3 straipsniai bei III skyrius  
*Medical Device Regulation 2017/745 Annex IX, Chapter I, Section 2 and 3 and Chapter III*

Notifikuotoji įstaiga / *Notified Body*

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg / Vokietija

CE 0197

Registracijos numeris / *Registration number:*

HZ 1198082-1


Versijos numeris / *Version number*

02

Pakeičia atitikties deklaraciją nuo /  
*Replaces Declaration of Conformity from*

20.09.2023

Hanau, 10.09.2025

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

Vieta, data / *Place, date*

Vardas, pavardė ir pareigos / *Name and function*

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



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

Medicinos prietaisas / *The medical device* **Heraenium – Non-precious metal alloys**

Versijos numeris / *Version number* 03

Pakeičia Priedą nuo / *Replaces Annex from* 10.09.2025

Šis straipsnių sąrašas tinka atitikties deklaracijai, kurios versija yra / *This article list is valid for the declaration of conformity version* 02

UDI-DI / <i>UDI-DI</i>	Prekės numeris / <i>Article number</i>	Pavadinimas / <i>Name</i>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

Vieta, data / *Place, date*

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

Vardas, pavardė ir pareigos / *Name and function*



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

Medicīniskā ierīce / *The medical device* **Heraenium – Non-precious metal alloys**

Versijas numurs / *Version number* 03

Aizstāj pielikumu, kas datēts ar / *Replaces Annex from* 10.09.2025

Šis izstrādājumu saraksts ir derīgs šādai atbilstības deklarācijas versijai / *This article list is valid for the declaration of conformity version* 02

<b>UDI-DI / UDI-DI</b>	<b>Preces numurs / Article number</b>	<b>Nosaukums / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hānava 11.02.2026

Vieta, datums / *Place, date*



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

Vārds, uzvārds un amats / *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*

**Heraenium – Non-precious metal alloys**

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*

Q10601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

van klasse / *of class*

IIa

in overeenstemming met regelgeving / *according to  
 rule*

8-1 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 22674 Dentistry - Metallic materials for fixed and removable  
 restorations and appliances  
 Voor overige toegepaste normen, zie technische documenten van  
 product Non-precious metal alloys, versie 02  
*Further Applied standards see Technical Documentation of Product  
 Non-precious metal alloys, Version 02*

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*

02

Vervangt de verklaring van conformiteit van /  
*Replaces Declaration of Conformity from*

20.09.2023

Hanau, 10.09.2025

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

Plaats, datum / *Place, date*

Naam en functie / *Name and function*

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

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

Het medisch hulpmiddel / <i>The medical device</i>	<b>Heraenium – Non-precious metal alloys</b>
Versienummer / <i>Version number</i>	03
Vervangt de bijlage van / <i>Replaces Annex from</i>	10.09.2025
Deze artikellijst is geldig voor de conformiteitsverklaring, versie / <i>This article list is valid for the declaration of conformity version</i>	02

Unieke identificatiecode / <i>UDI-DI</i>	Artikelnummer / <i>Article number</i>	Naam / <i>Name</i>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

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

**Heraenium – Non-precious metal alloys**

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

Q10601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

i klasse / of class

Ila

i henhold til regel / according to rule

8-1 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 22674 Dentistry - Metallic materials for fixed and removable restorations and appliances  
 Ytterligere anvendte standarder, se teknisk dokumentasjon for produktet Non-precious metal alloys, versjon 02  
 Further Applied standards see Technical Documentation of Product Non-precious metal alloys, Version 02

forordning 2017/745 om medisinsk utstyr vedlegg IX, kapittel I, avsnitt 2 og 3 og kapittel III

Prosedyre for samsvarsvurdering i henhold til /  
 Conformity assessment procedure acc. to

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

02

Erstatter samsvarserklæring fra /  
 Replaces Declaration of Conformity from

20.09.2023

Hanau, 10.09.2025

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

Sted, dato / Place, date

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.

**Liste over artikler / List of Articles**  
**Vedlegg / Annex: Samsvarserklæring / Declaration of Conformity**

Det medisinske utstyret / *The medical device* **Heraenium – Non-precious metal alloys**

Versjonsnummer / *Version number* 03

Erstatter vedlegg fra / *Replaces Annex from* 10.09.2025

Denne artikkellisten gjelder for samsvarserklæringsversjon / *This article list is valid for the declaration of conformity version* 02

<b>UDI-DI / UDI-DI</b>	<b>Artikkelnummer / Article number</b>	<b>Navn / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

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

**Heraenium – Non-precious metal alloys**

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

Q10601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

klasy / of class

IIa

zgodnie z regułą / according to rule

8-1 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 22674 Dentistry - Metallic materials for fixed and  
 removable restorations and appliances  
 Pozostałe stosowane normy znajdują się w dokumentacji  
 technicznej produktu Non-precious metal alloys, wersja 02  
 Further Applied standards see Technical Documentation of  
 Product Non-precious metal alloys, Version 02

Procedura oceny zgodności wg. /  
 Conformity assessment procedure acc. to

Rozporządzenie 2017/745 w sprawie wyrobów medycznych,  
 załącznik IX, rozdział I, sekcja 2 i 3 oraz rozdział III  
 Medical Device Regulation 2017/745 Annex IX, Chapter I, Section  
 2 and 3 and Chapter III

Jednostka notyfikowana / Notified Body

TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2  
 90431 Nürnberg/Niemcy

CE 0197

Numer rejestracyjny / Registration number:

HZ 1198082-1

Numer wersji / Version number

02

Zastępuje Deklarację zgodności z /  
 Replaces Declaration of Conformity from

20.09.2023

Hanau, 10.09.2025

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



Miejscowość, data / Place, date

Imię i nazwisko, stanowisko / Name and function

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



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

Wyrób medyczny / *The medical device* **Heraenium – Non-precious metal alloys**

Numer wersji / *Version number* 03

Zastępuje załącznik z dnia / *Replaces Annex from* 10.09.2025

Poniższa lista artykułów obowiązuje dla następujących wersji deklaracji zgodności / *This article list is valid for the declaration of conformity version* 02

UDI-DI / <i>UDI-DI</i>	Numer wyrobu / <i>Article number</i>	Nazwa / <i>Name</i>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

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 / **Kulzer GmbH**  
*Name and address of the company* Leipzig 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* **Heraenium – Non-precious metal alloys**

Nome, tipo ou modelo, número de lote ou de série, possivelmente origem e quantidade de itens / *List of articles, see Annex / List of Articles see Annex*  
*Name, type or model, batch or serial number, possibly sources and number of items*

Código EMDN / *EMDN-Code* Q10601  
 Código GMDN / *GMDN code* 35857  
 Código UMDNS / *UMDNS code* 16-661  
 UDI-DI básico / *Basic UDI-DI* ++J0141103NPMA0601aGJ

da classe / *of class* IIa  
 em conformidade com o regulamento / *according to rule* 8-1 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 22674 Dentistry - Metallic materials for fixed and removable restorations and appliances  
 Outras normas aplicadas, ver Documentação técnica do produto Non-precious metal alloys, Versão 02  
*Further Applied standards see Technical Documentation of Product Non-precious metal alloys, Version 02*

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* 02

Substitui a Declaração de Conformidade de / *Replaces Declaration of Conformity from* 20.09.2023

Hanau, 10.09.2025

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

Local, data / *Place, date* Nome e função / *Name and function*

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

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

O dispositivo médico / *The medical device* **Heraenium – Non-precious metal alloys**

Número de versão / *Version number* 03

Substitui o Anexo de / *Replaces Annex from* 10.09.2025

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* 02

<b>UDI-DI / UDI-DI</b>	<b>Número de artigo / Article number</b>	<b>Nome / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

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*

**Heraenium – Non-Precious Metal Alloys**

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*

Q010601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

din clasa / *of class*

Ila

în conformitate cu regula / *according to rule*

8-1 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 22674 Dentistry – Metallic materials for fixed and  
 removable restorations and appliances

Alte standarde aplicate, vezi documentația tehnică a Produsului  
 Non-Precious Metal Alloys, Versiunea 02 / *Further applied  
 standards see Technical Documentation of Product Non-Precious  
 Metal Alloys, 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*

20.09.2023



Hanau, 06.02.2026

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

Loc, dată / *Place, date*

Nume și funcție / *Name and function*

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

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

Dispozitivul medical / *The medical device* **Heraenium - Non-Precious Metal Alloys**

Număr versiune / *Version number* 03

Înlocuiește Anexa de la / *Replaces Annex from* 06.02.2026

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

<b>UDI-DI / UDI-DI</b>	<b>Număr articol / Article number</b>	<b>Nume / Name</b>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

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-00007705

**Vi försäkrar på eget ansvar att / We declare under our sole responsibility that**

den medicintekniska produkten / *the medical device* **Heraenium – Non-precious metal alloys**

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*

Q10601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

i klass / *of class*

Ila

enligt paragraf / *according to rule*

8-1 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 22674 Dentistry - Metallic materials for fixed and  
 removable restorations and appliances  
 För ytterligare tillämpade standarder, se teknisk dokumentation för  
 produkten Non-precious metal alloys, version 02  
*Further Applied standards see Technical Documentation of  
 Product Non-precious metal alloys, Version 02*

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*

02

Ersätter försäkran om överensstämmelse från /  
*Replaces Declaration of Conformity from*

20.09.2023

Hanau, 10.09.2025

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

Ort, datum / *Place, date*

Namn och funktion / *Name and function*

Denna försäkran om överensstämmelse är giltig i 2 år tillsammans med dokumenten för frisläppande av respektive  
 tillverkningsserie av medicintekniska produkter. / *This statement of conformity is valid for 2 years in connection with the release  
 documents for the respective batch of produced devices..*



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

Den medicintekniska produkten / *The medical device* **Heraenium – Non-precious metal alloys**

Versionsnummer / *Version number* 03

Ersätter bilaga från / *Replaces Annex from* 10.09.2025

Denna artikellista gäller för förklaring av *This article list is* 02  
 överensstämmelse version / *valid for the declaration of conformity version*

UDI-DI / <i>UDI-DI</i>	Artikelnummer / <i>Article number</i>	Namn / <i>Name</i>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

Ort, datum / *Place, date*

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

Namn och funktion / *Name and function*

## IZJAVA O SKLADNOSTI / DECLARATION OF CONFORMITY

Ime in naslov podjetja /  
 Name and address of the company

**Kulzer GmbH**  
 Leipziger Straße 2, 63450 Hanau  
 Nemčija / Germany  
 SRN: DE-MF-000007705

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

medicinski pripomoček / the medical device

**Heraenium – Non-Precious Metal Alloys**

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

Q010601  
 35857  
 16-661  
 ++J0141103NPMA0601aGJ

razreda / of class

Ila

v skladu s členom / according to rule

8-1 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 22674 Dentistry – Metallic materials for fixed and removable restorations and appliances

Drugi uveljavljeni standardi so na voljo v Tehnični dokumentaciji izdelka Non-Precious Metal Alloys, različica 02 / Further applied standards see Technical Documentation of Product Non-Precious Metal Alloys, Version 02

Postopek ugotavljanja skladnosti v skladu z /  
 Conformity assessment procedure acc. to

Uredbo o medicinskih pripomočkih 2017/745, Priloga IX, poglavje I, oddelek 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

20.09.2023

Hanau, 06.02.2026



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

Kraj, datum / Place, date

Ime in položaj / Name and function

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



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

Medicinski pripomoček / *The medical device* **Heraenium - Non-Precious Metal Alloys**

Številka različice / *Version number* 03

Nadomešča Prilogo z dne / *Replaces Annex from* 06.02.2026

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

UDI-DI / <i>UDI-DI</i>	Številka artikla / <i>Article number</i>	Ime / <i>Name</i>
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

Kraj, datum / *Place, date*

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

Ime in položaj / *Name and function*

## UYHLÁSENIE O ZHODE / DECLARATION OF CONFORMITY

Názov a adresa spoločnosti /  
*Name and address of the company*

**Kulzer GmbH**  
 Leipziger Straße 2, 63450 Hanau  
 Nemecko / Germany  
 SRN: DE-MF-000007705

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

zdravotnícka pomôcka / *the medical device*

**Heraenium – Non-Precious Metal Alloys**

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*

Q010601

Kód GMDN / *GMDN code*

35857

Kód UMDNS / *UMDNS code*

16-661

Základné identifikačné číslo UDI-DI / *Basic UDI-DI*

++J0141103NPMA0601aGJ

triedy / *of class*

Ila

podľa pravidla / *according to rule*

8-1 podľa prílohy VIII k nariadeniu 2017/745 o zdravotníckych pomôckach / *according to Annex VIII of Medical Device Regulation 2017/745*

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

Použité harmonizované normy, národné normy alebo iné normatívne dokumenty / *Applied harmonised standards, national standards or other normative documents*

EN ISO 22674 Dentistry – Metallic materials for fixed and removable restorations and appliances

Ďalšie použité normy nájdete v technickej dokumentácii verzie, 02 k produktu Non-Precious Metal Alloys / *Further applied standards see Technical Documentation of Product Non-Precious Metal Alloys, 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*

20.09.2023

Hanau, 06.02.2026

  
 i.V. 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 / The medical device	<b>Heraenium - Non-Precious Metal Alloys</b>
Číslo verzie / Version number	03
Nahrádza prílohu z / Replaces Annex from	06.02.2026
Tento zoznam tovaru je platný pre vyhlásenie o zhode, verzia / This article list is valid for the declaration of conformity version	02

UDI-DI / UDI-DI	Číslo položky / Article number	Meno / Name
+J014646009560	64600956	Heraenium EH (CoCr Alloy), 1000 g
+J014646009550	64600955	Heraenium CE (Chrome Cobalt), 1000 g
+J014646011790	64601179	Heraenium NF, Cr-Co Modelcast Alloy, 1 kg
+J014660022170	66002217	Heraenium P / 1 kg
+J014660024310	66002431	Heraenium P / 250 g
+J014660087900	66008790	Heraenium Laser / 1 kg
+J014646009570	64600957	Heraenium NA / 1kg
+J014660218710	66021871	Heraenium Pw, 1 kg
+J014660218720	66021872	Heraenium Pw, 250 g
+J014660019000	66001900	Heraenium S / 1 kg

Hanau, 11.02.2026

Miesto, dátum / Place, date



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

Meno a funkcia / Name and function