TŁUMACZENIE POŚWIADCZONE Z JĘZYKA ANGIELSKIEGO

[Wszystkie uwagi w nawiasach kwadratowych pochodzą od tłumaczki. Do tłumaczenia przedłożono skan dwujęzycznego dokumentu składającego się z trzech stron. Tłumaczenie obejmuje jedynie treści w języku angielskim.]

[*str. 1*]

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Jednostka notyfikowana 0373

[*logo z napisem:*] ISTITUTO SUPERIORE DI SANITA

Istituto Superiore di Sanità

Certyfikat nr **EPG-0201-19**	Załącznik nr **01-19**	Data pierwszego wydania	**22.02.2019 r.**
		Data aktualnego wydania	**21.03.2019 r.**
		Termin ważności	**21.02.2024 r.**

CERTYFIKAT
BADANIA PROJEKTU TYPU WE

zgodnie z Załącznikiem II (4) dyrektywy WE 93/42/EWG z dalszymi zmianami i ujednoliceniami

(wdrożonej we Włoszech dekretem ustawodawczym nr 46 wydanym dnia 24.02.1997 r. z dalszymi zmianami i ujednoliceniami)

Istituto Superiore di Sanità, Jednostka Notyfikowana 0373, zaświadcza, że dokumentacja projektowa dotycząca wyrobu medycznego

(patrz karta techniczna)

wyprodukowanego przez

GUNA S.p.A.

Siedziba:
Via Palmanova, 71-20132 Milano (MI) ITALIA
Inne zakłady Producenta:
Zakład produkcyjny: Via Palmanova, 69-20132 Milano (MI) Italia

została poddana weryfikacji, zgodnie z Załącznikiem II (4) dyrektywy WE 93/42/EWG z dalszymi zmianami i ujednoliceniami.

Dyrektor Jednostki Notyfikowanej
(Dr Roberta Marcoaldi)

(-) [*nieczytelny podpis*]

[*okrągła pieczęć z napisem w innym języku obcym*]

*** Karta techniczna stanowi integralną część niniejszego Certyfikatu.**

[*w stopce:*]

[*str. 2*]

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Jednostka notyfikowana 0373

[*logo z napisem:*] ISTITUTO SUPERIORE DI SANITA

Istituto Superiore di Sanità

KARTA TECHNICZNA

Certyfikat nr **EPG-0201-19** Załącznik nr **01-19,**

którego integralną część stanowi niniejsza karta techniczna, odnosi się wyłącznie do następujących wyrobów objętych nadzorem:

Klasa: III	
Nazwa produktu	**Kod**
Collagen Hip [kolagen na biodra] *GUNA 01, MD-HIP, GUNA-HIP, ПЛЕКСАТРОН, PLEXATHRON*	*MD 01*
Collagen Ischial [kolagen na dolny odcinek kręgosłupa] *GUNA 02, MD-ISCHIAL, GUNA-ISCHIAL*	*MD 02*
Collagen Knee [kolagen na kolana] *GUNA 03, MD-KNEE, GUNA-KNEE*	*MD 03*
Collagen Lumbar [kolagen na lędźwiowy odcinek kręgosłupa] *GUNA 04, MD-LUMBAR, GUNA-LUMBAR*	*MD 04*
Collagen Muscle [kolagen na mięśnie] *GUNA 06, MD-MUSCLE, GUNA-MUSCLE*	*MD 06*
Collagen Neck [kolagen na szyjny odcinek kręgosłupa] *GUN-A 07, MD-NECK GUNA-NECK, ОСТЕОКОЛЛ, OSTEOCOLL*	*MD 07*
Collagen Neural [kolagen na układ nerwowy] *GUNA 08, MD-NEURAL, GUNA-NEURAL*	*MD 08*
Collagen Poly [kolagen wielorakiego zastosowania] *GUNA 09, MD-POLY, GUNA-POLY*	*MD 09*
Collagen Shoulder [kolagen na bark] *GUNA 10, MD-SHOULDER, GUNA-SHOULDER*	*MD 10*
Collagen Small Joints [kolagen na stawy drobne] *GUNA 11, MD-SMALL JOINTS, GUNA-SMALL JOINTS, GUNA-HAND FOOT, MD-HAND FOOT*	*MD 11*
Collagen Thoracic [kolagen na piersiowy odcinek kręgosłupa] *GUNA 12, MD-THORACIC, GUNA-THORACIC*	*MD 12*

Dyrektor Jednostki Notyfikowanej
(Dr Roberta Marcoaldi)

(-) [*nieczytelny podpis*]

[*okrągła pieczęć z napisem w innym języku obcym*]

[*w stopce:*]

[*str. 3*]

Mod. 2201 – ISS

Jednostka notyfikowana 0373

[*logo z napisem:*] ISTITUTO SUPERIORE DI SANITA

Istituto Superiore di Sanità

KARTA TECHNICZNA

Certyfikat nr **EPG-0201-19** Załącznik nr **01-19**

którego integralną część stanowi niniejsza karta techniczna, odnosi się wyłącznie do następujących wyrobów objętych nadzorem:

Klasa: III	
Nazwa produktu	**Kod**
Collagen Matrix [*kolagen Matrix*] *GUNA 05, MD-MATRIX, GUNA-MATRIX*	*MD 05*
Collagen Tissue [*kolagen na tkanki*] *GUNA 13, MD-TISSUE, GUNA-TISSUE, GUNA-MADE, MD-MADE*	*MD 13*

Ocena zgodności: MOD-341-01-01 nr 48/19

Niniejszy certyfikat zastępuje poprzedni certyfikat EPG 0201 19 wydany dnia 22.02.2019 r.

Dyrektor Jednostki Notyfikowanej
(Dr Roberta Marcoaldi)

(-) [*nieczytelny podpis*]

[*okrągła pieczęć z napisem w innym języku obcym*]

[*w stopce:*]

Poświadczam zgodność powyższego tłumaczenia z okazanym mi skanem dokumentu w języku angielskim.

Dorota Plutecka, tłumacz przysięgły języka angielskiego, wpisana na listę tłumaczy przysięgłych, prowadzoną przez Ministra Sprawiedliwości, pod numerem TP/38/18.

Numer w repertorium: 522/2022

Kraków, dnia 4 maja 2022 r.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° *Certificate no.* **EPG-0201-19**

Addendum n° *addendum no.* **01-19**

Data prima emissione *First issue date* **22.02.2019**
Data di emissione corrente *Current issue date* **21.03.2019**
Data di scadenza *Expiry date* **21.02.2024**

ESAME CE DELLA PROGETTAZIONE DEL PRODOTTO

secondo l'Allegato II (4) della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

EC DESIGN-EXAMINATION CERTIFICATE

according to Annex II (4) of EC Directive 93/42/EEC and subsequent modifications and integrations
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il fascicolo di progettazione del dispositivo medico

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the design dossier relating to the medical device

*(vedi allegato tecnico/ see technical sheet)**

fabbricato da *manufactured by*

GUNA S.p.A.

Sede Legale/ Registered Office:
Via Palmanova, 71 – 20132 Milano (MI) ITALIA

Altre sedi del Fabbricante /Other sites of the Manufacturer:
Sede Produttiva/ Production Site: Via Palmanova, 69 – 20132 Milano (MI) Italia

è stato sottoposto a verifica, conformemente ai requisiti dell'Allegato II (4), della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

has been submitted to verification, according to Annex II (4), of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

* L'allegato tecnico è parte integrante del presente Certificato
The technical sheet is an integral part of this Certificate.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **EPG-0201-19**

Addendum n° / *addendum no.* **01-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe *(Class)*: III	
Nome prodotto *(product name)*	***Codice*** *(Code)*
Collagen Hip *GUNA 01, MD-HIP, GUNA-HIP, ПЛЕКСАТРОН, PLEXATHRON*	*MD 01*
Collagen Ischial *GUNA 02, MD-ISCHIAL, GUNA-ISCHIAL*	*MD 02*
Collagen Knee *GUNA 03, MD-KNEE, GUNA-KNEE*	*MD 03*
Collagen Lumbar *GUNA 04, MD-LUMBAR, GUNA-LUMBAR*	*MD 04*
Collagen Muscle *GUNA 06, MD-MUSCLE, GUNA-MUSCLE*	*MD 06*
Collagen Neck *GUNA 07, MD-NECK, GUNA-NECK, ОСТЕОКОЛЛ, OSTEOCOLL*	*MD 07*
Collagen Neural *GUNA 08, MD-NEURAL, GUNA-NEURAL*	*MD 08*
Collagen Poly *GUNA 09, MD-POLY, GUNA-POLY*	*MD 09*
Collagen Shoulder *GUNA 10, MD-SHOULDER, GUNA-SHOULDER*	*MD 10*
Collagen Small Joints *GUNA 11, MD-SMALL JOINTS, GUNA-SMALL JOINTS, GUNA-HAND FOOT, MD-HAND FOOT*	*MD 11*
Collagen Thoracic *GUNA 12, MD-THORACIC, GUNA-THORACIC*	*MD 12*

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no. **EPG-0201-19**

Addendum n°
addendum no. **01-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe *(Class)*: III	
Nome prodotto *(product name)*	***Codice*** *(Code)*
Collagen Matrix *GUNA 05, MD-MATRIX, GUNA-MATRIX*	*MD 05*
Collagen Tissue *GUNA 13, MD-TISSUE, GUNA-TISSUE, GUNA-MADE, MD-MADE*	*MD 13*

Valutazione della conformità: vedi MOD-341-01-01 n° 48/19
Conformity assessment : MOD-341-01-01 n. 48/19

Il presente certificato annulla e sostituisce il certificato EPG 0201 19 del 22/02/2019.
This certificate supersedes the previous certificate EPG 0201 19 issued on 22/02/2019.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

GUNA S.p.a.
Via Palmanova, 71
20132 Milano - Italia

Tel. +39.02.28018.1
PEC: guna@legalmail.it
info@guna.it

DECLARATION OF CONFORMITY

CE

According to Directive 93/42/CEE (amendment 2007/47/CE) implemented in Italy with D.lgs 46/97 (amendment D. lgs 37/2010) and Regulation (UE) 2017/745 UE article 120

The Manufacturer: Guna S.p.a.

Legal address: via Palmanova 71 – 20132 Milano, Italy
Manufacturing site: via Palmanova 69 – 20132 Milano, Italy

Scope: GUNA COLLAGEN MEDICAL DEVICES
solution for injection
Medical Devices Class III
MD 0204-Non active soft tissues implants, sterile

Conformity assessment procedure: Annex II - Directive 93/42 EEC and ss.mm.ii.

Products	**Code**	**National registration N.**	**GMDN**	**CND**
Collagen Hip Other brand names: Guna 01, MD-Hip, Guna-Hip, Плексатрон, Plexathron, Плексатрон, Plexathron, ПЛЕКСАТРОН плюс, PLEXATHRON PLUS, DENTAL BONE BIOREGULATION	MD 01	302644	33525	P900401
Collagen Ischial Other brand names: Guna 02, MD-Ischial, Guna-Ischial	MD 02	303280	33525	P900401
Collagen Knee Other brand names: Guna 03, MD-Knee, Guna-Knee	MD 03	303284	33525	P900401
Collagen Lumbar Other brand names: Guna 04, MD-Lumbar, Guna-Lumbar	MD 04	303286	33525	P900401
Collagen Matrix Other brand names:	MD 05	301833	33525	P900401

GUNA S.p.a.
Via Palmanova, 71
20132 Milano - Italia

Tel. +39.02.28018.1
PEC: guna@legalmail.it
info@guna.it

Guna 05, MD-Matrix, Guna-Matrix				
Collagen Muscle Other brand names: Guna 06, MD-Muscle, Guna-Muscle, Dental ATM Bioregulation	MD 06	303288	33525	P900401
Collagen Neck Other brand names: Guna 07, MD-Neck, Guna-Neck, Остеоколл, Osteocoll, ОСТЕОКОЛЛ ПЛЮ, OSTEOCOLL PLUS	MD 07	303292	33525	P900401
Collagen Neural Other brand names: Guna 08, MD-Neural, Guna-Neural	MD 08	303294	33525	P900401
Collagen Poly Other brand names: Guna 09, MD-Poly, Guna-Poly	MD 09	303301	33525	P900401
Collagen Shoulder Other brand names: Guna 10, MD-Shoulder, Guna-Shoulder	MD 10	303303	33525	P900401
Collagen Small Joints Other brand names: Guna 11, MD-Small Joints, Guna-Small Joints, Guna-Hand Foot, MD-Hand Foot	MD 11	303304	33525	P900401
Collagen Thoracic Other brand names: Guna 12, MD-Thoracic, Guna-Thoracic	MD 12	303305	33525	P900401
Collagen Tissue Other brand names: Guna 13, MD-Tissue, Guna-Tissue, Guna-Made, MD-Made, Dental Skin Bioregulation	MD 13	302624	33525	P900401

CE certificate nr.

EPG-0201-19, addendum 02-19
EC design-examination certificate
issued by Istituto Superiore di Sanità (ISS) – N.B. 0373
valid up to 31/12/2027 according to EU Regulation 607/2023.

QCT-0114-19, addendum 02-19
EC declaration of conformity full quality assurance system
issued by Istituto Superiore di Sanità (ISS) – N.B. 0373
valid up to 31/12/2027 according to EU Regulation 607/2023.

GUNA S.p.a.
Via Palmanova, 71
20132 Milano - Italia

Tel. +39.02.28018.1
PEC: guna@legalmail.it
info@guna.it

THE MANUFACTURER DECLARES

under its sole responsibility that the medical devices of the range GUNA COLLAGEN MEDICAL DEVICES, listed above

- ✓ satisfy the essential requirements in annex I of Directive 93/42/CEE (amendment 2007/47/CE) implemented in Italy with D.lgs 46/97 (amendment D. lgs 37/2010)

- ✓ comply with all requirements and applicable provisions of Directive 93/42/CEE (amendment 2007/47/CE) implemented in Italy with D.lgs 46/97 (amendment D. lgs 37/2010), applicable parts according to Regulation (EU) 2017/745 as modified by Regulation (EU) 2023/607.

- ✓ starting from 26 May 2021, comply with all requirements and applicable provisions of MDR 2017/745 Regulation (EU) 2017/745 as modified by Regulation (EU) 2023/607.

- ✓ comply with all other applicable EU implementing acts, technical specifications, harmonised rules and national requirements

- ✓ are placed on the market bearing the CE marking according to Art. 17 of Directive 93/42/EEC as amended and implements in Italy by Legislative Decree 46/97, and according to Article 120 paragraph 3a of Regulation (EU) 2017/745.

- ✓ meet the conditions of Article 120 paragraph 3c of Regulation (EU) 2017/745, as modified by Regulation (EU) 2023/607, for placing on the market up to 31/12/2027.

The manufacturer commits to retain the technical documentation, the declaration of conformity and certificates for a period of at least 15 years after the last device has been placed on the market, and keep it available for the competent authorities in case of request.

Milano, 11/03/2024

Alessandro Pizzoccaro
Legal representative
Guna S.p.a.

TŁUMACZENIE POŚWIADCZONE Z JĘZYKA ANGIELSKIEGO

[*Wszystkie uwagi w nawiasach kwadratowych pochodzą od tłumaczki. Do tłumaczenia przedłożono skan dwujęzycznego dokumentu składającego się z trzech stron. Tłumaczenie obejmuje jedynie treści w języku angielskim.*]

[*str. 1*]

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Jednostka notyfikowana 0373

[*logo z napisem:*] ISTITUTO SUPERIORE DI SANITA

Istituto Superiore di Sanità

Certyfikat nr **QCT-0114-19**	Załącznik nr **01-19**	Data pierwszego wydania	**22.02.2019 r.**
		Data aktualnego wydania	**21.03.2019 r.**
		Termin ważności	**21.02.2024 r.**

DEKLARACJA ZGODNOŚCI WE

SYSTEM CAŁKOWITEGO ZAPEWNIENIA JAKOŚCI

zgodnie z Załącznikiem II z wyłączeniem (4) dyrektywy WE 93/42/EWG z dalszymi zmianami i ujednoliceniami

(wdrożonej we Włoszech dekretem ustawodawczym nr 46 wydanym dnia 24.02.1997 r. z dalszymi zmianami i ujednoliceniami)

Istituto Superiore di Sanità, Jednostka Notyfikowana 0373, zaświadcza, że system całkowitego zapewnienia jakości wdrożony przez

GUNA S.p.A.

Siedziba:
Via Palmanova, 71-20132 Milano (MI) ITALIA

Inne zakłady Producenta:

Zakład produkcyjny: Via Palmanova, 69-20132 Milano (MI) Italia

dla urządzenia/urządzeń

(patrz karta techniczna)

jest zgodny z obowiązującymi wymogami Dyrektywy Rady 93/42/EWG z dalszymi zmianami i ujednoliceniami.

Dyrektor Jednostki Notyfikowanej
(Dr Roberta Marcoaldi)

(-) [*nieczytelny podpis*]

[*okrągła pieczęć z napisem w innym języku obcym*]

*** Karta techniczna stanowi integralną część niniejszego Certyfikatu.**

[*w stopce:*]

[*str. 2*]

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Jednostka notyfikowana 0373

[*logo z napisem:*] ISTITUTO SUPERIORE DI SANITA

Istituto Superiore di Sanità

KARTA TECHNICZNA

Certyfikat nr **QCT-0114-19** Załącznik nr **01-19,**

którego integralną część stanowi niniejsza karta techniczna, odnosi się wyłącznie do następujących wyrobów objętych nadzorem:

Klasa: III	
Nazwa produktu	**Kod**
Collagen Hip [kolagen na biodra] *GUNA 01, MD-HIP, GUNA-HIP, ПЛЕКСАТРОН, PLEXATHRON*	*MD 01*
Collagen Ischial [kolagen na dolny odcinek kręgosłupa] *GUNA 02, MD-ISCHIAL, GUNA-ISCHIAL*	*MD 02*
Collagen Knee [kolagen na kolana] *GUNA 03, MD-KNEE, GUNA-KNEE*	*MD 03*
Collagen Lumbar [kolagen na lędźwiowy odcinek kręgosłupa] *GUNA 04, MD-LUMBAR, GUNA-LUMBAR*	*MD 04*
Collagen Muscle [kolagen na mięśnie] *GUNA 06, MD-MUSCLE, GUNA-MUSCLE*	*MD 06*
Collagen Neck [kolagen na szyjny odcinek kręgosłupa] *GUN-A 07, MD-NECK, GUNA-NECK, ОСТЕОКОЛЛ, OSTEOCOLL*	*MD 07*
Collagen Neural [kolagen na układ nerwowy] *GUNA 08, MD-NEURAL, GUNA-NEURAL*	*MD 08*
Collagen Poly [kolagen wielorakiego zastosowania] *GUNA 09, MD-POLY, GUNA-POLY*	*MD 09*
Collagen Shoulder [kolagen na bark] *GUNA 10, MD-SHOULDER, GUNA-SHOULDER*	*MD 10*
Collagen Small Joints [kolagen na stawy drobne] *GUNA 11, MD-SMALL JOINTS, GUNA-SMALL JOINTS, GUNA-HAND FOOT, MD-HAND FOOT*	*MD 11*
Collagen Thoracic [kolagen na piersiowy odcinek kręgosłupa] *GUNA 12, MD-THORACIC, GUNA-THORACIC*	*MD 12*

Dyrektor Jednostki Notyfikowanej
(Dr Roberta Marcoaldi)

(-) [*nieczytelny podpis*]

[*okrągła pieczęć z napisem w innym języku obcym*]

[*w stopce:*]

[*str. 3*]

Mod. 2201 – ISS

Jednostka notyfikowana 0373

[*logo z napisem:*] ISTITUTO SUPERIORE DI SANITA

Istituto Superiore di Sanità

KARTA TECHNICZNA

Certyfikat nr **QCT-0114-19** Załącznik nr **01-19**

którego integralną część stanowi niniejsza karta techniczna, odnosi się wyłącznie do następujących wyrobów objętych nadzorem:

Klasa: III	
Nazwa produktu	**Kod**
Collagen Matrix [*kolagen Matrix*] *GUNA 05, MD-MATRIX, GUNA-MATRIX*	*MD 05*
Collagen Tissue [*kolagen na tkanki*] *GUNA 13, MD-TISSUE, GUNA-TISSUE, GUNA-MADE, MD-MADE*	*MD 13*

Ocena zgodności: MOD-341-01-01 nr 48/19

Niniejszy certyfikat zastępuje poprzedni certyfikat QCT 0114 19 wydany dnia 22.02.2019 r.

Dyrektor Jednostki Notyfikowanej
(Dr Roberta Marcoaldi)

(-) [*nieczytelny podpis*]

[*okrągła pieczęć z napisem w innym języku obcym*]

[*w stopce:*]

Poświadczam zgodność powyższego tłumaczenia z okazanym mi skanem dokumentu w języku angielskim.

Dorota Plutecka, tłumacz przysięgły języka angielskiego, wpisana na listę tłumaczy przysięgłych, prowadzoną przez Ministra Sprawiedliwości, pod numerem TP/38/18.

Numer w repertorium: 523/2022

Kraków, dnia 4 maja 2022 r.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° *Certificate no.* **QCT-0114-19**

Addendum n° *addendum no.* **01-19**

Data prima emissione *First issue date*	**22.02.2019**
Data di emissione corrente *Current issue date*	**21.03.2019**
Data di scadenza *Expiry date*	**21.02.2024**

DICHIARAZIONE CE DI CONFORMITA' SISTEMA COMPLETO DI GARANZIA DI QUALITA'

secondo l'Allegato II escluso (4) della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

EC DECLARATION OF CONFORMITY FULL QUALITY ASSURANCE SYSTEM

according to Annex II excluding (4) of EC Directive 93/42/EEC and subsequent modifications and integrations.
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il sistema completo di garanzia della qualità attuato da

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the total quality assurance system enforced by

GUNA S.p.A.

Sede Legale/ Registered Office:
Via Palmanova, 71 – 20132 Milano (MI) ITALIA

Altre sedi del Fabbricante /Other sites of the Manufacturer:

Sede Produttiva/ Production Site: ***Via Palmanova, 69 – 20132 Milano (MI) Italia***

per il dispositivo/i *for the device(s)*

(vedi allegato tecnico/ see technical sheet)*

è conforme ai requisiti applicabili della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

is in compliance with the applicable requirements of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

* L'allegato tecnico è parte integrante del presente Certificato
The technical sheet is an integral part of this Certificate.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QCT-0114-19**

Addendum n° / *addendum no.* **01-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe *(Class)*: **III**	
Nome prodotto *(product name)*	***Codice*** *(Code)*
Collagen Hip *GUNA 01, MD-HIP, GUNA-HIP, ПЛЕКСАТРОН, PLEXATHRON*	*MD 01*
Collagen Ischial *GUNA 02, MD-ISCHIAL, GUNA-ISCHIAL*	*MD 02*
Collagen Knee *GUNA 03, MD-KNEE, GUNA-KNEE*	*MD 03*
Collagen Lumbar *GUNA 04, MD-LUMBAR, GUNA-LUMBAR*	*MD 04*
Collagen Muscle *GUNA 06, MD-MUSCLE, GUNA-MUSCLE*	*MD 06*
Collagen Neck *GUNA 07, MD-NECK, GUNA-NECK, ОСТЕОКОЛЛ, OSTEOCOLL*	*MD 07*
Collagen Neural *GUNA 08, MD-NEURAL, GUNA-NEURAL*	*MD 08*
Collagen Poly *GUNA 09, MD-POLY, GUNA-POLY*	*MD 09*
Collagen Shoulder *GUNA 10, MD-SHOULDER, GUNA-SHOULDER*	*MD 10*
Collagen Small Joints *GUNA 11, MD-SMALL JOINTS, GUNA-SMALL JOINTS, GUNA-HAND FOOT, MD-HAND FOOT*	*MD 11*
Collagen Thoracic *GUNA 12, MD-THORACIC, GUNA-THORACIC*	*MD 12*

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO

Il Certificato n°
The Certificate no. **QCT-0114-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

TECHNICAL SHEET

Addendum n°
addendum no. **01-19**

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe *(Class)*: **III**	
Nome prodotto *(product name)*	***Codice*** *(Code)*
Collagen Matrix *GUNA 05, MD-MATRIX, GUNA-MATRIX*	*MD 05*
Collagen Tissue *GUNA 13, MD-TISSUE, GUNA-TISSUE, GUNA-MADE, MD-MADE*	*MD 13*

Valutazione della conformità: vedi MOD-341-01-01 n° 48/19
Conformity assessment : MOD-341-01-01 n. 48/19

Il presente certificato annulla e sostituisce il certificato QCT 0114 19 del 22/02/2019.
This certificate supersedes the previous certificate QCT 0114 19 issued on 22/02/2019.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° *Certificate no.* **QCT-0114-19**

Addendum n° *addendum no.* **02-19**

Data prima emissione *First issue date*	**22.02.2019**
Data di emissione corrente *Current issue date*	**03.07.2019**
Data di scadenza *Expiry date*	**21.02.2024**

DICHIARAZIONE CE DI CONFORMITA' SISTEMA COMPLETO DI GARANZIA DI QUALITA'

secondo l'Allegato II escluso (4) della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

EC DECLARATION OF CONFORMITY FULL QUALITY ASSURANCE SYSTEM

according to Annex II excluding (4) of EC Directive 93/42/EEC and subsequent modifications and integrations.
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il sistema completo di garanzia della qualità attuato da

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the total quality assurance system enforced by

GUNA S.p.A.

***Sede Legale/** Registered Office:*
Via Palmanova, 71 – 20132 Milano (MI) ITALIA

Altre sedi del Fabbricante /Other sites of the Manufacturer:
Sede Produttiva/** Production Site: **Via Palmanova, 69 – 20132 Milano (MI) Italia

per il dispositivo/i *for the device(s)*

(vedi allegato tecnico/ see technical sheet)*

è conforme ai requisiti applicabili della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

is in compliance with the applicable requirements of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

* **L'allegato tecnico è parte integrante del presente Certificato**
The technical sheet is an integral part of this Certificate.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QCT-0114-19**

Addendum n° / *addendum no.* **02-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe III (Class III)

Nome prodotto (Product name)	**Codice** (Code)
Collagen Hip GUNA 01, MD-HIP, GUNA-HIP, ПЛЕКСАТРОН, PLEXATHRON, Dental BONE BioRegulation	MD 01
Collagen Ischial GUNA 02, MD-ISCHIAL, GUNA-ISCHIAL	MD 02
Collagen Knee GUNA 03, MD-KNEE, GUNA-KNEE	MD 03
Collagen Lumbar GUNA 04, MD-LUMBAR, GUNA-LUMBAR	MD 04
Collagen Muscle GUNA 06, MD-MUSCLE, GUNA-MUSCLE, Dental ATM BioRegulation	MD 06
Collagen Neck GUNA 07, MD-NECK, GUNA-NECK, ОСТЕОКОЛЛ, OSTEOCOLL	MD 07
Collagen Neural GUNA 08, MD-NEURAL, GUNA-NEURAL	MD 08
Collagen Poly GUNA 09, MD-POLY, GUNA-POLY	MD 09
Collagen Shoulder GUNA 10, MD-SHOULDER, GUNA-SHOULDER	MD 10

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcaldi)

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QCT-0114-19**

Addendum n° / *addendum no.* **02-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

***Classe III** (Class III)*

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Collagen Small Joints *GUNA 11, MD-SMALL JOINTS, GUNA-SMALL JOINTS, GUNA-HAND FOOT, MD-HAND FOOT*	*MD 11*
Collagen Thoracic *GUNA 12, MD-THORACIC, GUNA-THORACIC*	*MD 12*
Collagen Matrix *GUNA 05, MD-MATRIX, GUNA-MATRIX*	*MD 05*
Collagen Tissue *GUNA 13, MD-TISSUE, GUNA-TISSUE, GUNA-MADE, MD-MADE, Dental SKIN BioRegulation*	*MD 13*

Valutazione della conformità: vedi MOD-341-01-01 n° 221/19
Conformity assessment : MOD-341-01-01 n. 221/19

Il presente certificato sostituisce il certificato QCT 0114 19 01 19 del 21/03/2019.
This certificate supersedes the previous certificate QCT 0114 19 01 19 issued on 21/03/2019.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

TŁUMACZENIE POŚWIADCZONE Z JĘZYKA ANGIELSKIEGO

[Wszystkie uwagi w nawiasach kwadratowych pochodzą od tłumaczki. Do tłumaczenia przedłożono skan dwujęzycznego dokumentu składającego się z trzech stron. Tłumaczenie obejmuje jedynie treści w języku angielskim.]

[*str. 1*]

Mod. 2201 – ISS

Jednostka notyfikowana 0373

[*logo z napisem:*] ISTITUTO SUPERIORE DI SANITA

Istituto Superiore di Sanità

Certyfikat nr **EPG-0201-19**	Załącznik nr **01-19**	Data pierwszego wydania	**22.02.2019 r.**
		Data aktualnego wydania	**21.03.2019 r.**
		Termin ważności	**21.02.2024 r.**

CERTYFIKAT
BADANIA PROJEKTU TYPU WE

zgodnie z Załącznikiem II (4) dyrektywy WE 93/42/EWG z dalszymi zmianami i ujednoliceniami

(wdrożonej we Włoszech dekretem ustawodawczym nr 46 wydanym dnia 24.02.1997 r. z dalszymi zmianami i ujednoliceniami)

Istituto Superiore di Sanità, Jednostka Notyfikowana 0373, zaświadcza, że dokumentacja projektowa dotycząca wyrobu medycznego

(patrz karta techniczna)

wyprodukowanego przez

GUNA S.p.A.

Siedziba:
Via Palmanova, 71-20132 Milano (MI) ITALIA
Inne zakłady Producenta:
Zakład produkcyjny: Via Palmanova, 69-20132 Milano (MI) Italia

została poddana weryfikacji, zgodnie z Załącznikiem II (4) dyrektywy WE 93/42/EWG z dalszymi zmianami i ujednoliceniami.

Dyrektor Jednostki Notyfikowanej
(Dr Roberta Marcoaldi)

(-) [*nieczytelny podpis*]

[*okrągła pieczęć z napisem w innym języku obcym*]

*** Karta techniczna stanowi integralną część niniejszego Certyfikatu.**

[*w stopce:*]

[*str. 2*]

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Jednostka notyfikowana 0373

[*logo z napisem:*] ISTITUTO SUPERIORE DI SANITA

Istituto Superiore di Sanità

KARTA TECHNICZNA

Certyfikat nr **EPG-0201-19** Załącznik nr **01-19,**

którego integralną część stanowi niniejsza karta techniczna, odnosi się wyłącznie do następujących wyrobów objętych nadzorem:

Klasa: III	
Nazwa produktu	**Kod**
Collagen Hip [kolagen na biodra] *GUNA 01, MD-HIP, GUNA-HIP, ПЛЕКСАТРОН, PLEXATHRON*	*MD 01*
Collagen Ischial [kolagen na dolny odcinek kręgosłupa] *GUNA 02, MD-ISCHIAL, GUNA-ISCHIAL*	*MD 02*
Collagen Knee [kolagen na kolana] *GUNA 03, MD-KNEE, GUNA-KNEE*	*MD 03*
Collagen Lumbar [kolagen na lędźwiowy odcinek kręgosłupa] *GUNA 04, MD-LUMBAR, GUNA-LUMBAR*	*MD 04*
Collagen Muscle [kolagen na mięśnie] *GUNA 06, MD-MUSCLE, GUNA-MUSCLE*	*MD 06*
Collagen Neck [kolagen na szyjny odcinek kręgosłupa] *GUN-A 07, MD-NECK GUNA-NECK, ОСТЕОКОЛЛ, OSTEOCOLL*	*MD 07*
Collagen Neural [kolagen na układ nerwowy] *GUNA 08, MD-NEURAL, GUNA-NEURAL*	*MD 08*
Collagen Poly [kolagen wielorakiego zastosowania] *GUNA 09, MD-POLY, GUNA-POLY*	*MD 09*
Collagen Shoulder [kolagen na bark] *GUNA 10, MD-SHOULDER, GUNA-SHOULDER*	*MD 10*
Collagen Small Joints [kolagen na stawy drobne] *GUNA 11, MD-SMALL JOINTS, GUNA-SMALL JOINTS, GUNA-HAND FOOT, MD-HAND FOOT*	*MD 11*
Collagen Thoracic [kolagen na piersiowy odcinek kręgosłupa] *GUNA 12, MD-THORACIC, GUNA-THORACIC*	*MD 12*

Dyrektor Jednostki Notyfikowanej
(Dr Roberta Marcoaldi)

(-) [*nieczytelny podpis*]

[*okrągła pieczęć z napisem w innym języku obcym*]

[*w stopce:*]

[*str. 3*]

Mod. 2201 – ISS

Jednostka notyfikowana 0373

[*logo z napisem:*] ISTITUTO SUPERIORE DI SANITA

Istituto Superiore di Sanità

KARTA TECHNICZNA

Certyfikat nr **EPG-0201-19** Załącznik nr **01-19**

którego integralną część stanowi niniejsza karta techniczna, odnosi się wyłącznie do następujących wyrobów objętych nadzorem:

Klasa: III	
Nazwa produktu	**Kod**
Collagen Matrix [*kolagen Matrix*] *GUNA 05, MD-MATRIX, GUNA-MATRIX*	*MD 05*
Collagen Tissue [*kolagen na tkanki*] *GUNA 13, MD-TISSUE, GUNA-TISSUE, GUNA-MADE, MD-MADE*	*MD 13*

Ocena zgodności: MOD-341-01-01 nr 48/19

Niniejszy certyfikat zastępuje poprzedni certyfikat EPG 0201 19 wydany dnia 22.02.2019 r.

Dyrektor Jednostki Notyfikowanej
(Dr Roberta Marcoaldi)

(-) [*nieczytelny podpis*]

[*okrągła pieczęć z napisem w innym języku obcym*]

[*w stopce:*]

Poświadczam zgodność powyższego tłumaczenia z okazanym mi skanem dokumentu w języku angielskim.

Dorota Plutecka, tłumacz przysięgły języka angielskiego, wpisana na listę tłumaczy przysięgłych, prowadzoną przez Ministra Sprawiedliwości, pod numerem TP/38/18.

Numer w repertorium: 522/2022

Kraków, dnia 4 maja 2022 r.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° *Certificate no.* **EPG-0201-19**

Addendum n° *addendum no.* **01-19**

Data prima emissione *First issue date* **22.02.2019**
Data di emissione corrente *Current issue date* **21.03.2019**
Data di scadenza *Expiry date* **21.02.2024**

ESAME CE DELLA PROGETTAZIONE DEL PRODOTTO

secondo l'Allegato II (4) della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

EC DESIGN-EXAMINATION CERTIFICATE

according to Annex II (4) of EC Directive 93/42/EEC and subsequent modifications and integrations
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il fascicolo di progettazione del dispositivo medico

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the design dossier relating to the medical device

*(vedi allegato tecnico/ see technical sheet)**

fabbricato da *manufactured by*

GUNA S.p.A.

Sede Legale/ Registered Office:
Via Palmanova, 71 – 20132 Milano (MI) ITALIA

Altre sedi del Fabbricante /Other sites of the Manufacturer:
Sede Produttiva/ Production Site: Via Palmanova, 69 – 20132 Milano (MI) Italia

è stato sottoposto a verifica, conformemente ai requisiti dell'Allegato II (4), della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

has been submitted to verification, according to Annex II (4), of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

* L'allegato tecnico è parte integrante del presente Certificato
The technical sheet is an integral part of this Certificate.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **EPG-0201-19**

Addendum n° / *addendum no.* **01-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe *(Class)*: III	
Nome prodotto *(product name)*	***Codice*** *(Code)*
Collagen Hip *GUNA 01, MD-HIP, GUNA-HIP, ПЛЕКСАТРОН, PLEXATHRON*	*MD 01*
Collagen Ischial *GUNA 02, MD-ISCHIAL, GUNA-ISCHIAL*	*MD 02*
Collagen Knee *GUNA 03, MD-KNEE, GUNA-KNEE*	*MD 03*
Collagen Lumbar *GUNA 04, MD-LUMBAR, GUNA-LUMBAR*	*MD 04*
Collagen Muscle *GUNA 06, MD-MUSCLE, GUNA-MUSCLE*	*MD 06*
Collagen Neck *GUNA 07, MD-NECK, GUNA-NECK, ОСТЕОКОЛЛ, OSTEOCOLL*	*MD 07*
Collagen Neural *GUNA 08, MD-NEURAL, GUNA-NEURAL*	*MD 08*
Collagen Poly *GUNA 09, MD-POLY, GUNA-POLY*	*MD 09*
Collagen Shoulder *GUNA 10, MD-SHOULDER, GUNA-SHOULDER*	*MD 10*
Collagen Small Joints *GUNA 11, MD-SMALL JOINTS, GUNA-SMALL JOINTS, GUNA-HAND FOOT, MD-HAND FOOT*	*MD 11*
Collagen Thoracic *GUNA 12, MD-THORACIC, GUNA-THORACIC*	*MD 12*

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no. **EPG-0201-19**

Addendum n°
addendum no. **01-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe *(Class)*: III	
Nome prodotto *(product name)*	***Codice*** *(Code)*
Collagen Matrix *GUNA 05, MD-MATRIX, GUNA-MATRIX*	*MD 05*
Collagen Tissue *GUNA 13, MD-TISSUE, GUNA-TISSUE, GUNA-MADE, MD-MADE*	*MD 13*

Valutazione della conformità: vedi MOD-341-01-01 n° 48/19
Conformity assessment : MOD-341-01-01 n. 48/19

Il presente certificato annulla e sostituisce il certificato EPG 0201 19 del 22/02/2019.
This certificate supersedes the previous certificate EPG 0201 19 issued on 22/02/2019.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° *Certificate no.* **EPG-0201-19**

Addendum n° *addendum no.* **02-19**

Data prima emissione *First issue date*	**22.02.2019**
Data di emissione corrente *Current issue date*	**03.07.2019**
Data di scadenza *Expiry date*	**21.02.2024**

ESAME CE DELLA PROGETTAZIONE DEL PRODOTTO

secondo l'Allegato II (4) della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

EC DESIGN-EXAMINATION CERTIFICATE

according to Annex II (4) of EC Directive 93/42/EEC and subsequent modifications and integrations
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il fascicolo di progettazione del dispositivo medico

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the design dossier relating to the medical device

*(vedi allegato tecnico/ see technical sheet)**

fabbricato da *manufactured by*

GUNA S.p.A.

***Sede Legale/** Registered Office:*
Via Palmanova, 71 – 20132 Milano (MI) ITALIA

Altre sedi del Fabbricante /Other sites of the Manufacturer:
Sede Produttiva/** Production Site: **Via Palmanova, 69 – 20132 Milano (MI) Italia

è stato sottoposto a verifica, conformemente ai requisiti dell'Allegato II (4), della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

has been submitted to verification, according to Annex II (4), of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcaldi)

Roberta Marcaldi

* **L'allegato tecnico è parte integrante del presente Certificato**
The technical sheet is an integral part of this Certificate.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **EPG-0201-19**

Addendum n.° / *addendum no.* **02-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

***Classe III** (Class III)*

Nome prodotto *(Product name)*
Collagen Hip — *GUNA 01, MD-HIP, GUNA-HIP, ПЛЕКСАТРОН, PLEXATHRON, Dental BONE BioRegulation*
Collagen Ischial — *GUNA 02, MD-ISCHIAL, GUNA-ISCHIAL*
Collagen Knee — *GUNA 03, MD-KNEE, GUNA-KNEE*
Collagen Lumbar — *GUNA 04, MD-LUMBAR, GUNA-LUMBAR*
Collagen Muscle — *GUNA 06, MD-MUSCLE, GUNA-MUSCLE, Dental ATM BioRegulation*
Collagen Neck — *GUNA 07, MD-NECK, GUNA-NECK, ОСТЕОКОЛЛ, OSTEOCOLL*
Collagen Neural — *GUNA 08, MD-NEURAL, GUNA-NEURAL*
Collagen Poly — *GUNA 09, MD-POLY, GUNA-POLY*
Collagen Shoulder — *GUNA 10, MD-SHOULDER, GUNA-SHOULDER*

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcaldi)

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **EPG-0201-19**

Addendum n° / *addendum no.* **02-19**

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

***Classe III** (Class III)*

Nome prodotto *(Product name)*
Collagen Small Joints *GUNA 11, MD-SMALL JOINTS, GUNA-SMALL JOINTS, GUNA-HAND FOOT, MD-HAND FOOT*
Collagen Thoracic *GUNA 12, MD-THORACIC, GUNA-THORACIC*
Collagen Matrix *GUNA 05, MD-MATRIX, GUNA-MATRIX*
Collagen Tissue *GUNA 13, MD-TISSUE, GUNA-TISSUE, GUNA-MADE, MD-MADE, Dental SKIN BioRegulation*

Valutazione della Conformità: MOD-341-01-01 n° 221/19
Conformity assessment: MOD-341-01-01 n. 221/19

Il presente certificato sostituisce il certificato EPG 0201 19 01 19 del 21/03/2019
This certificate supersedes the previous certificate EPG 0201 19 01 19 issued on 21/03/2019

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcaldi)

GUNA S.p.a.
Via Palmanova, 71
20132 Milano - Italy
Tel. +39.02.28018.1
Fax ordini +39.02.28018.449
www.gunainternational.com - e-mail: export@guna.it

Milano, 27/03/2024

To whom it may concern

The Manufacturer Guna S.p.a., legal address at via Palmanova 71 – 20132 Milano, Italy and manufacturing site at via Palmanova 69 – 20132 Milano, Italy

DECLARES

That the products of the range "GUNA COLLAGEN MEDICAL DEVICES", Medical Devices Class III listed below, comply with Directive 93/42/EEC.

Product name	**Product Code**	**Registration number**	**GMDN nomenclature**	**CND classification**
MD-Hip	MD 01	302644	33525	P900401
MD- Ischial	MD 02	303280	33525	P900401
MD- Knee	MD 03	303284	33525	P900401
MD- Lumbar	MD 04	303286	33525	P900401
MD- Muscle	MD 06	303288	33525	P900401
MD- Neck	MD 07	303292	33525	P900401
MD- Neural	MD 08	303294	33525	P900401
MD- Poly	MD 09	303301	33525	P900401
MD- Shoulder	MD 10	303303	33525	P900401
MD- Small Joints	MD 11	303304	33525	P900401
MD- Thoracic	MD 12	303305	33525	P900401
MD- Matrix	MD 05	301833	33525	P900401
MD- Tissue	MD 13	302624	33525	P900401
Conformity assessment procedure Annex II - Directive 93/42 EEC CE certificate nr. EPG-0201-19, addendum 02-19 and QCT-0114-19, addendum 02-19				

Sofia Pizzoccaro
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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Guna S.p.a.
Manufacturer address and contact details	Via Palmanova 71, 20132 Milan – Italy Tel. +39 02280181 Email: info@guna.it
Single Registration Number (SRN)	IT-MF-000010167

Notified body name	☒ See attached schedule
Notified body number	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made	☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificates** (see attached schedule) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificates,** as listed in the attached schedule, covering the listed devices, were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.

They expire *after* 20 March 2023 (on 21 February 2024):

- Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us (on 24 November 2022) to a notified body before 26 May 2024 for some of the devices listed in attached schedule (15 devices) and signed written agreement is in place (from 22 December 2022) in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024. Therefore, for those devices, the transition period will end on 31 December 2027 (see attached schedule).
- We do not intent to lodge an application for conformity assessment by 26 May 2024 for some other devices (11 devices) listed in attached schedule. Therefore, for those devices, the transition period will end on 26 May 2024 (see attached schedule).

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR is in place.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Guna S.p.a.

Milan, 19th July 2023

Sofia Pizzoccaro

PRRC

Email: so.pizzoccaro@guna.it; Tel: 02 28018451

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Collagen Hip (MD 01)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Ischial (MD 02)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Knee (MD 03)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.

Collagen Lumbar (MD 04)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Matrix (MD 05)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Muscle (MD 06)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Neck (MD 07)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.

Collagen Neural (MD 08)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Poly (MD 09)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Shoulder (MD 10)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Small Joints (MD 11)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.

Collagen Thoracic (MD 12)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Tissue (MD 13)	QCT-0114-19 Addendum n° 02-19 EPG-0201-19 Addendum n° 02-19	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Hip H (MD 01 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-
Collagen Ischial H (MD 02 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-

Collagen Knee H (MD 03 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.
Collagen Lumbar H (MD 04 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-
Collagen Matrix H (MD 05 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-
Collagen Muscle H (MD 06 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-

Collagen Neck H (MD 07 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-
Collagen Neural H (MD 08 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-
Collagen Poly H (MD 09 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-
Collagen Shoulder H (MD 10 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-

Collagen Small Joints H (MD 11 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-
Collagen Thoracic H (MD 12 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	No application for conformity assessment before 26th May 2024	26th May 2024	-
Collagen Tissue H (MD 13 H)	QCT-0114-19 Addendum n° 03-21 EPG-0201-19 Addendum n° 03-21	21st February 2024	Istituto Superiore di Sanità (n.0373)	Istituto Superiore di Sanità (n.0373)	31st December 2027	N.A.

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To whom it may concern

TSE/BSE DECLARATION

With reference to the medical devices of Guna S.p.a., listed below (class III, sterile) CE Mark released by the Notified Body 0373 ISS (Istituto Superiore di Sanità) and manufactured by Guna S.p.a.

MD brand name in use	MD generic name	Product code
MD-HIP	Collagen Hip	MD 01
MD-ISCHIAL	Collagen Ischial	MD 02
MD-KNEE	Collagen Knee	MD 03
MD-LUMBAR	Collagen Lumbar	MD 04
MD-MATRIX	Collagen Matrix	MD 05
MD-MUSCLE	Collagen Muscle	MD 06
MD-NECK	Collagen Neck	MD 07
MD-NEURAL	Collagen Neural	MD 08
MD-POLY	Collagen Poly	MD 09
MD-SHOULDER	Collagen Shoulder	MD 10
MD-SMALL JOINTS	Collagen Small Joints	MD 11
MD-THORACIC	Collagen Thoracic	MD 12
MD-TISSUE	Collagen Tissue	MD 13

we hereby state and declare that:

- None of the products listed above contains ingredients derived from cattle, sheep or goat.
- All the raw materials used for production do not contain any material which may be risky (skull, brain, spinal bone marrow, spinal column, eyes, glands and organ derivatives from cattle, sheep or goat) and are free from the risk of transmitting animal spongiform encephalopathy agents (TSE/BSE) - in compliance with European directive 2003/32/CE of 23 April 2003 and subsequent updates and changes.
- the products listed above are produced in compliance with the requirements set forth in:
  - European Decision 97/534/ CE of 30 July 1997 and subsequent updates and changes.
  - Note for guidance on minimising the risk oftransmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 Rev. 3 July 2011).

Therefore we certify that the medical devices listed above are manufactured using ingredients free from risk of TSE/BSE.

Milano, 7th september 2022

Sofia Pizzoccaro
Regulatory Affairs Director
Guna S.p.a.