



EC CERTIFICATE

Certificate No 1924/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

GT MEDICAL S.L.

28031 MADRID - C/LUIS I 94, 2 Planta Local 8 (ESP) - Spain

manages in the factory of:

28031 MADRID - C/ Luis I, 94, 1º, Local 13 (ESP) - Spain

28031 MADRID - C/LUIS I, 71, NAVE 12 (ESP) - Spain

28031 MADRID - Camino de Hormigueras 122bis,3 Pl. P1-P2 (ESP) - Spain

28031 MADRID - Camino de Hormigueras, 122-3ª P., Nave L (ESP) - Spain

a quality assurance system ensuring the conformity of the following products:

Abutment

Healing abutment

Abutments and prosthetic accessories

Screws and dental prosthetic

Dental pre-milled

Type ref. as to document "Annex of EC Certificate no. 1924/MDD - Device List" rev. 0 dated 2021/03/30; this annex is integral and substantial part of this certificate.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM15A0571104-01; DM18-0022447-01; DM20-0049047-01; DM20-0049212-01; DM21-0061801-01.

Date: 2017-02-14
 Updated: 2021-03-30
 Substitution Date: 2020-06-03
 Expiry Date: 2024-05-26

IMQ



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Certificate No 1924/MDD

Full Quality Assurance System Approval Certificate

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 2017-02-14
Updated: 2021-03-30
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CERTIFICATE N. 9190.GTME
CERTIFICADO N.

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY
CERTIFICA QUE EL SISTEMA DE CALIDAD DE

GT-MEDICAL, S.L.

C/LUIS I, 94 PLANTA 1 LOCAL 13 - 28031 MADRID SPAIN

OPERATIVE UNITS / INSTALACIÓN DE

View the Annex for the Operative Units (n. 4 pages)
Ver el Anexo para las Unidades Operativas (n. 4 páginas)

IS IN COMPLIANCE WITH THE STANDARD / REÚNE LOS REQUISITOS DE LA NORMA
ISO 9001:2015

FOR THE FOLLOWING ACTIVITIES / PARA LAS SIGUIENTES ACTIVIDADES
Design, manufacture, marketing, distribution, import and export of
medical devices and materials of dental sector

Diseño, fabricación, comercialización, distribución, importación y exportación
de productos sanitarios y materiales del sector dental

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization
Cualquier aclaración adicional relativa a la aplicación de la norma ISO 9001:2015, puede obtenerse consultando a la organización

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS
EL PRESENTE CERTIFICADO ESTÁ SUJETO AL RESPETO DEL REGLAMENTO
PARA LA CERTIFICACIÓN DE LOS SISTEMAS DE GESTIÓN

DATES:	FIRST CERTIFICATION PRIMERA CERTIFICACIÓN	CURRENT ISSUE EMISION ACTUAL	EXPIRY VÁLIDO HASTA
	2014-06-25	2020-04-22	2023-06-24

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Omago



SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 17, 29

The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years
La validez del certificado está sujeta a auditorias anuales y a la recertificación completa del Sistema de Gestión con una periodicidad trienal



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CERTIFICATE N. 9124.GTM2
CERTIFICADO N.

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY
CERTIFICA QUE EL SISTEMA DE CALIDAD DE

GT-MEDICAL, S.L.

C/LUIS I, 94 PLANTA 1 LOCAL 13 - 28031 MADRID SPAIN

OPERATIVE UNITS / INSTALACIÓN DE

View the Annex for the Operative Units (n. 4 pages)
Ver el Anexo para las Unidades Operativas (n. 4 páginas)

IS IN COMPLIANCE WITH THE STANDARD / REÚNE LOS REQUISITOS DE LA NORMA
ISO 13485:2016

FOR THE FOLLOWING ACTIVITIES / PARA LAS SIGUIENTES ACTIVIDADES

Design, development, manufacture of dental pre-milled, prosthetic abutments and dental surgical instruments. Importation of dental medical devices
Diseño, desarrollo, fabricación de patillas de fresado, aditamentos protésicos e instrumental quirúrgico dental. Importación de productos sanitarios del sector dental

Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization
Cualquier aclaración adicional relativa a la aplicación de la norma ISO 13485:2016, puede obtenerse consultando a la organización

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS
EL PRESENTE CERTIFICADO ESTÁ SUJETO AL RESPETO DEL REGLAMENTO
PARA LA CERTIFICACIÓN DE LOS SISTEMAS DE GESTIÓN

DATES:	FIRST CERTIFICATION PRIMERA CERTIFICACIÓN 2014-06-25	CURRENT ISSUE EMISION ACTUAL 2020-04-22	EXPIRY VÁLIDO HASTA 2023-06-24
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ANNEX N. 9124.GTM2-1
ANNEXO N°

GT-MEDICAL, S.L.

C/ LUIS I, 94 2ª PLANTA LOCAL 8 - 28031 MADRID SPAIN

Activities:
Actividades:

Warehouse and distribution
Almacén y distribución

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO GT-MEDICAL, S.L.
EL OBJETIVO DEL ANEXO ES EXPLICAR LAS ACTIVIDADES REALIZADAS EN CADA SEDE / UNIDAD OPERATIVA DE LA CERTIFICACIÓN DEL SISTEMA DE GESTIÓN EMITIDA A GT-MEDICAL, S.L.

FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE NR. 9124.GTM2
PARA LA FECHA DE CADUCIDAD, VER EL CERTIFICADO NR. 9124.GTM2

DATES:	FIRST CERTIFICATION PRIMERA CERTIFICACIÓN	CURRENT ISSUE EMISION ACTUAL	EXPIRY VÁLIDO HASTA
	2014-06-25	2020-04-22	2023-06-24

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ANNEX N. 9124.GTM2-2
ANNEXO N°

GT-MEDICAL, S.L.

C/ LUIS I, 71 NAVE 12 - 28031 MADRID SPAIN

Activities:
Actividades:

Dental pre -milled manufacture
Fabricación de pastillas de fresado

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Este documento es parte del certificado n. 9124.GTM2

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ANNEX N. 9124.GTM2-3
ANNEXO N°

GT-MEDICAL, S.L.

CAMINO DE HORMIGUERAS 122 BIS P1-P2 - 28031 MADRID SPAIN

Activities:
Actividades:

Design, development, manufacture of dental pre-milled, prothetic abutments and dental surgical instruments. Importation of dental medical devices
Diseño, desarrollo, fabricación, de pastillas de fresado, aditamentos protésicos e instrumental quirúrgico dental. Importación de productos sanitarios del sector dental

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO GT-MEDICAL, S.L.
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ANNEX N. 9124.GTM2-4
ANNEXO N°

GT-MEDICAL, S.L.

CAMINO DE HORMIGUERAS 122 PLANTA 3 NAVE L - 28031 MADRID SPAIN

Activities:
Actividades:

Abutments manufacture and dimensional control
Fabricación de aditamentos dentales y control dimensional.

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CE Certificado Europeo de Producto Sanitario.

Invertimos anualmente 1.000.000 euros en I+D+I (Investigación + Desarrollo + Innovación) con el fin de estar en la vanguardia de las tendencias del sector, así como de las últimas tecnologías.

De esta forma, logramos la Calidad de nuestros Productos tanto de clínica, como de laboratorio (materiales, recubrimientos, ajuste, estética y comodidad para el paciente), siempre probados a través de estudios.

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