ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD

Italia

CERTIFICATO

Nr 50 100 5344 - Rev. 04

Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

C.G.M. S.p.A. DIVISIONE MEDICALE META

SEDE LEGALE: / *REGISTERED OFFICE:*

VIA MODENA 22/24 I-42015 CORREGGIO (RE)

SEDE OPERATIVA: / *OPERATIONAL SITE:*

VIA E. VILLA 7 I-42124 REGGIO EMILIA (RE)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2008

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medici monouso per infusione, raccolta sangue, neonatologia, ginecologia, chirurgia e cateterismo vescicale, sacche urina ed urinometri, strumenti chirurgici e dispositivi per implantologia ossea (IAF 14, 17)

Design and development, production and distribution of medical disposables for infusion, blood collection, neonatology, gynecology, surgery and vescical catheterism, urine bags and urinometers, surgical instruments and devices for bone implantology (IAF 14, 17)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A	SSI N° 005G	PRD N° 081B
SGA N° 018D	ITX N° 001L	ISP N° 057E
SCR N° 009F	PRS N° 077C	LAB N° 0076

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

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Claus Spallinger

Claus Spallinger
Direttore Systems & Compliance

Validità / *Validity*

Dal / From: **2014-10-14**

Al / To: **2017-10-13**

Data emissione / *Printing Date*

2014-10-31

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2003-07-03

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

T101-14/01

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America

CERTIFICATE

No. QS1 14 09 32687 028

Certificate Holder: C.G.M. s.p.a. Divisione Medicale META
Via E. Villa, 7
42124 Reggio Emilia
ITALY

Certification Mark:

Scope of Certificate: Design, Production and Distribution of Medical Disposables for Infusion, Blood Collection, Neonatology, Gynecology, Surgery and Vescical Catheterism, Urine Bags and Urimeters, Surgical Instruments for Bone Implantology

Standard(s): ISO 13485:2003

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

TÜV SÜD America Inc. is a Health Canada CMDCAS Recognized Registrar.

Report No.: M2712

Effective Date: 2014-12-01
Expiry Date: 2017-11-30

Gary Minks
Vice President, Regulatory Affairs

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

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SCC Accredited CB-MS OCSM Accrédité CCN

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 14 10 32687 030

Holder of Certificate: **C.G.M. s.p.a. Divisione Medicale META**
Via E. Villa, 7
42124 Reggio Emilia
ITALY

Facility(ies): C.G.M. s.p.a. Divisione Medicale META
Via E. Villa, 7, 42124 Reggio Emilia, ITALY

Certification Mark:

Scope of Certificate: **Design and development, production and distribution of medical disposables for infusion, blood collection, neonatology, gynecology, surgery and vescical catheterism, urine bags and urinometers, surgical instruments and devices for bone implantology**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA247632

Valid from: 2014-10-31
Valid until: 2017-10-30

603901

Date, 2014-10-30

Hans-Heiner Junker

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 13 04 32687 027

Manufacturer:

C.G.M. s.p.a. Divisione Medicale META
Via E. Villa, 7
42124 Reggio Emilia
ITALY

Facility(ies):

C.G.M. s.p.a. Divisione Medicale META
Via E. Villa, 7, 42124 Reggio Emilia, ITALY

Product Category(ies):

Urine bags, magnetic mats for surgical instruments, umbilical clamps, postnatal kits, device for vacuum infusion of granulated biomaterials

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: ITA 231986

Valid from: 2013-05-15
Valid until: 2018-05-14

Date, 2013-05-15

Hans-Heiner Junker

520934

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 02 32687 032

Manufacturer:

C.G.M. s.p.a. Divisione Medicale META
Via E. Villa, 7
42124 Reggio Emilia
ITALY

Facility(ies):

C.G.M. s.p.a. Divisione Medicale META
Via E. Villa, 7, 42124 Reggio Emilia, ITALY

Product Category(ies):

Bone scraper and bone grafting collector, set for dental osteotome, surgical dental drills, device for infusion and hydratation of granulated biomaterials, membrane fixation tacks, membrane tacks positioner, tweezer to evaluate flap tension for gum tissues.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA266257

Valid from: 2016-03-04
Valid until: 2018-05-14

Date, 2016-03-04

Stefan Preiß

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