



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 15 06 21697 017

Manufacturer: **EnviteC - Wismar GmbH**
Alter Holzhafen 18
23966 Wismar
GERMANY

Facility(ies): EnviteC - Wismar GmbH
Alter Holzhafen 18, 23966 Wismar, GERMANY

Product Category(ies): **Oxygen Saturation Sensors and Monitors,
Sensors and Control Units for Monitoring of
Respiratory Parameters and Gas Exchange,
Non-invasive Blood Pressure Equipment,
Temperature Sensors**

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.: 713063594

Valid from: 2015-09-02
Valid until: 2020-09-01



Date, 2015-08-28

Hans-Heiner Junker

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

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Oxygen Sensor OOM201

Use the advantages:

- Compliant with European MDD (CE certification)
- Meets ISO 80601-2-55
- Designed and manufactured according to EN ISO 13485
- Accurate and reliable fast response
- Resistant to N₂O
- Excellent signal stability
- High product quality
- Short delivery times
- Technical support
- Made in Germany
- FDA cleared



From standard sensors to customized sensors

Experienced EnviteC engineers analyze customer requirements. This input is used for different standard and OEM applications, and ongoing support is provided right up to the final integrator in the solution. EnviteC designs customized sensors characterized by a maximum possible degree of precision, for example with different signal levels or temperature compensation elements.

Intendend use

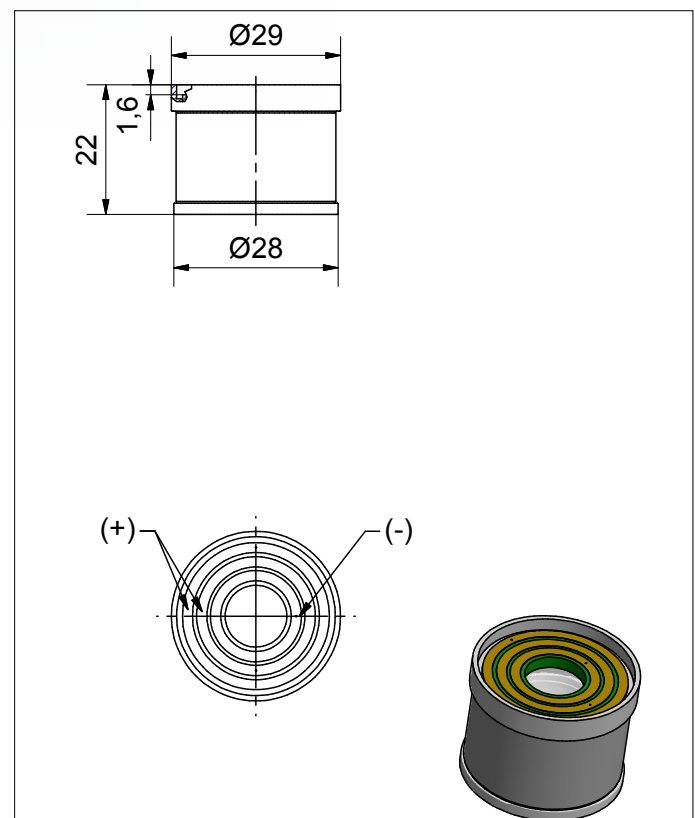
The EnviteC Medical Oxygen Sensors are intended as oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications:

Sensing device for oxygen in

- control device of oxygen concentrators
- medical ventilators
- anaesthesia equipment
- incubators.

The use is limited to system monitoring. The sensors are not suited for breath by breath analysis of breath gases. Please refer to the Instructions for Use! If the sensor is intended to replace the original oxygen-sensing component of an oxygen analyzer, consult the EnviteC XRL Cross Reference List for selecting the appropriate sensor.

Mechanical drawing (All dimension in mm)



General tolerances ISO 2768-c



Additional information

The Instructions for Use as well as the EnviteC XRL Cross Reference List are available under www.EnviteC.com and in the Apple App Store under EnviteC XRL as free download.

For more information please contact us!

We look forward to assisting you either on the phone or in a personal talk.

Technical Specifications OOM201

Measurement range	0 % ... 100 % oxygen (at atmospheric pressure)
Nominal sensor lifetime	≥ 500 000 % volume oxygen hours
Output in ambient air	14 mV ... 20.7 mV (Dual Cathode), load 600 Ohms
Electrical interface	Gold plated slip rings
Accuracy	meets ISO 80601-2-55 requirements
Repeatability	< 1 % volume O ₂ at constant temperature and pressure
Linearity error	< 3 % relative
Response time	< 12 s to 90 % of final value
Zero offset voltage	< 200 µV in 100 % nitrogen, applied for 5 min
Cross interference	meets ISO 80601-2-55 requirements
Influence of humidity	-0.03 % rel. per % RH at 25 °C
Pressure range	0.6 bar ... 2 bar (ppO ₂ 0 ... 1250 mbar O ₂)
Influence of pressure	proportional to change in oxygen partial pressure
Influence of mechanical shock	< 1 % relative after a fall from 1 m
Operating temperature	0 °C ... +50 °C
Temperature compensation	no temperature compensation
Operating humidity	0 % ... 99 % RH non-condensing
Long term output drift	< 1 % volume oxygen per month typically < -15 % relative over lifetime
Storage temperature	-20 °C ... +50 °C
Recommended storage	+5 °C ... +15 °C
Recommended load	≥ 10 kOhms
Warm-up time	< 30 minutes, after replacement of sensor
Weight	approximately 28 grams
Part number	01-00-0014

All specifications are applicable at standard conditions:
1013 hPa, 25 °C dry ambient air



For suitable accessories and sensors please refer to the EnviteC Cross Reference List under www.EnviteC.com and in the Apple App Store under EnviteC XRL as free download.

EnviteC-Wismar GmbH a Honeywell Company

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Doc. No. 001-33-Datasheet_OOM201-0

March 2016

Technical information is subject
to change without notice!

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specifications and adjust its production
at any time and without notice.

ENVITEC
by Honeywell

Oxygen Sensor OOM103-1

Use the advantages:

- Compliant with European MDD (CE certification)
- Meets ISO 80601-2-55
- Designed and manufactured according to EN ISO 13485
- Accurate and reliable response
- Resistant to N₂O
- Excellent signal stability
- High product quality
- Short delivery times
- Technical support
- Made in Germany
- FDA cleared



From standard sensors to customized sensors

Experienced EnviteC engineers analyze customer requirements. This input is used for different standard and OEM applications, and ongoing support is provided right up to the final integrator in the solution. EnviteC designs customized sensors characterized by a maximum possible degree of precision, for example with different signal levels or temperature compensation elements.

Intendend use

The EnviteC Medical Oxygen Sensors are intended as oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications:

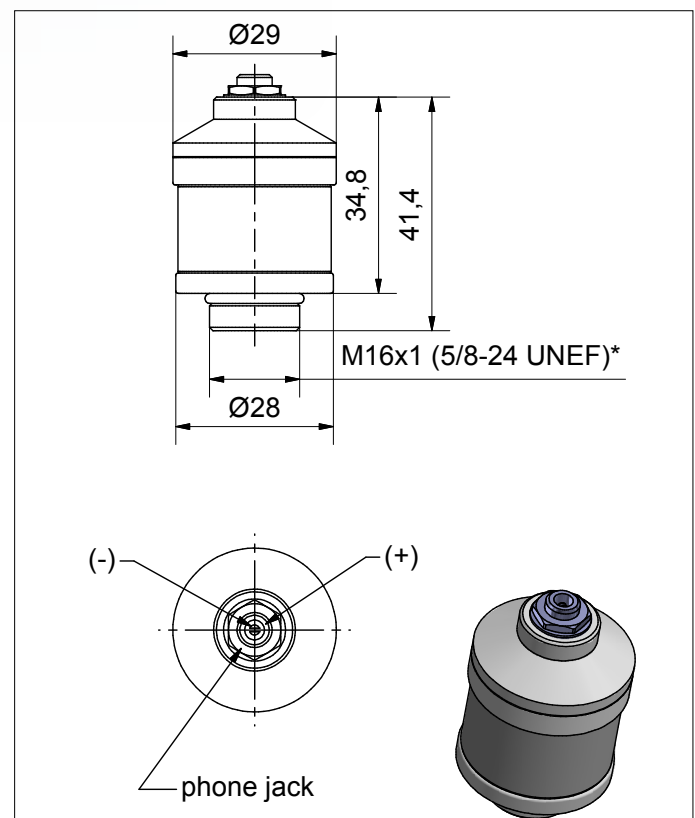
Sensing device for oxygen in

- control device of oxygen concentrators
- medical ventilators
- anaesthesia equipment
- incubators.

The use is limited to system monitoring. The sensors are not suited for breath by breath analysis of breath gases. Please refer to the Instructions for Use! If the sensor is intended to replace the original oxygen-sensing component of an oxygen analyzer, consult the EnviteC XRL Cross Reference List for selecting the appropriate sensor.



Mechanical drawing (All dimension in mm)



General tolerances ISO 2768-c

*Intermediate thread: Metric / Unified Extra Fine

Additional information

The Instructions for Use as well as the EnviteC XRL Cross Reference List are available under www.EnviteC.com and in the Apple App Store under EnviteC XRL as free download.

For more information please contact us!

We look forward to assisting you either on the phone or in a personal talk.

Technical Specifications OOM103-1

Measurement range	0 % ... 100 % oxygen (at atmospheric pressure)
Nominal sensor lifetime	≥ 500 000 % volume oxygen hours
Output in ambient air	9 mV ... 13 mV
Electrical interface	3.5 mm mono phone Jack
Accuracy	meets ISO 80601-2-55 requirements
Repeatability	< 1 % volume O ₂ at constant temperature and pressure
Linearity error	< 3 % relative
Response time	< 5 s to 90 % of final value
Zero offset voltage	< 100 µV in 100 % nitrogen, applied for 5 min
Cross interference	meets ISO 80601-2-55 requirements
Influence of humidity	-0.03 % rel. per % RH at 25 °C
Pressure range	0.6 bar ... 2 bar (ppO ₂ 0 ... 1250 mbar O ₂)
Influence of pressure	proportional to change in oxygen partial pressure
Influence of mechanical shock	< 1 % relative after a fall from 1 m
Operating temperature	0 °C ... +50 °C
Temperature compensation	built-in NTC compensation
Effect of temperature compensation (steady state)	between +25 °C and +40 °C: 3 % relative error between 0 °C and +50 °C: 8 % relative error
Operating humidity	0 % ... 99 % RH non-condensing
Long term output drift	< 1 % volume oxygen per month typically < -15 % relative over lifetime
Storage temperature	-20 °C ... +50 °C
Recommended storage	+5 °C ... +15 °C
Recommended load	≥ 10 kOhms
Warm-up time	< 30 minutes, after replacement of sensor
Weight	approximately 28 grams
Part number	01-00-0016

All specifications are applicable at standard conditions:

1013 hPa, 25 °C dry ambient air



For suitable accessories and sensors please refer to the EnviteC Cross Reference List under www.EnviteC.com and in the Apple App Store under EnviteC XRL as free download.

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Doc. No. 001-33-Datasheet_OOM103_1-0

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specifications and adjust its production
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ENVITEC
by Honeywell



Product Service

CERTIFICATE

No. Q5 17 12 21697 018

Holder of Certificate: **EnviteC - Wismar GmbH**

Alter Holzhafen 18
23966 Wismar
GERMANY

Facility(ies):

EnviteC - Wismar GmbH
Alter Holzhafen 18, 23966 Wismar, GERMANY

Certification Mark:



Scope of Certificate:

Design and development, production and distribution of sensors and control units for monitoring of vital physiological parameters, sensors and control units for monitoring of respiratory mechanics parameters and gas exchange, measurement devices and sensors for alcohol blood concentration

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

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.: 713119332

Valid from: 2018-02-06

Valid until: 2021-01-30



S. Preis

Stefan Preis

Date, 2018-02-06

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GIMA

CRILE WOOD NEEDLE HOLDER - 15 cm

Code: 26852
Category: Needle holders
Unit of sale: 1 pc.
Minimum order: 1
Type: Medical device
Class: I
NSIS: 142068
CND: L0205
EAN13: 8023279268522



Description: STAINLESS STEEL CRILE WOOD NEEDLE HOLDER.

Instructions: GB, FR, IT, ES, PT, DE, GR, Arabic.



GIMA



ADULT MOUTHPIECES - disposable

Code: 33410

Category: Peak flow meters - asthma

Unit of sale: box of 500 pcs.

Minimum order: 1

Type: Medical device

Class: II A

NSIS: 49378

CND: R9001

EAN13: 8023279334104

Description: Paper mouthpieces (disposable) suitable for most brands of spirometers and peak flow meters. Individually packed in transparent pouch.

Technical Specifications:

- **Material:** paper
- **Size (Ø int x Ø est x h):** 2.8 x 3 x 6.5 cm (adult)
- **For GIMA codes:** 33431, 33433, 33471-2, 33510, 33512-14, 33518-22, 33528-32, 33534
- **Compatible with:** Micromedical Vitalograph, Mir Ferraris (Koko legend) Cardiette (Pneumos 300)

Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	20
Primo rilascio / First issue date	2006-10-25	Valido da / Valid from	2016-10-24
Scadenza / Valid until	2021-10-24	Ultima modifica / Last change date	2016-11-07

Certificato CE del Sistema di Garanzia della Qualità/ EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

GIMA S.p.A.

sede operativa / Operational Headquarter:

Via Marconi, 1
20060 Gessate, MI - Italia

sede legale

Via Tommaso Grossi, 2
Milano - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*

Bilancia ad uso medicale / *Scales for medical use*

Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

Dispositivi per aerosolterapia / *Nebulizer therapy devices*

Dispositivi per la misurazione della saturazione di O₂ / *Oxygen saturation measuring devices*

Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Dispositivi per misurazione / *Measuring devices*

Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Dispositivi per terapia termica / *Thermic therapy devices*

Elettrocardiografi / *Electrocardiographs*

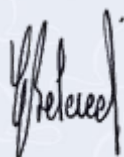
Sfigmomanometri / *Sphygmomanometers*

Rif. rapporto di audit/ *Ref. audit report:* 19-20-21/09/2016

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* ==

Rif. analisi dossier progettazione/ *Ref. design dossier analysis:* ==

Chief Operating Officer
Giampiero Belcredi



Organismo Notificato n. 0476

Notified Body nr. 0476

Certificate

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1106

Marca / Brandname:

GIMA

Modello / Model:

Aspiratori e accessori / *aspirators and accessories*

Tipologia / Medical Devices:

Bilancia ad uso medicale / *Scales for medical use*

Classe di rischio / Risk class:

I m

Codice NANDO / NANDO codes:

MD 0104

Marca / Brandname:

GIMA

Modello / Model:

ASTRA - FAMILY - PEGASO

Tipologia / Medical Devices:

Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

Classe di rischio / Risk class:

I s

Codice NANDO / NANDO codes:

MD 7006

Marca / Brandname:

GIMA

Modello / Model:

Jimabrush

Chief Operating Officer
Giampiero Belcredi



Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

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Scadenza / Valid until	2021-10-24	Ultima modifica / Last change date	2016-11-07

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

Marca / Brandname:

GIMA

Modello / Model:

Cervical Spoon

Modello / Model:

Cervix Brush Plush

Modello / Model:

Gima Collector

Modello / Model:

Gimabrush Ball

Modello / Model:

Kit ORL sterile / *Sterile ENT kit*

Modello / Model:

Kit pap test / *Pap smear kit*

Modello / Model:

Spatula legno sterile / *Sterile wooden spatula*

Modello / Model:

Spatula plastica sterile / *Sterile plastic spatula*

Modello / Model:

Speculum perno - mix / *Vaginal Speculum central pin - mix*

Modello / Model:

Speculum perno centrale - grande / *Vaginal Speculum central pin- large*

Modello / Model:

Speculum perno centrale - medio / *Vaginal Speculum central pin - medium*

Modello / Model:

Speculum perno centrale - piccolo / *Vaginal Speculum central pin - small*

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

Marca / Brandname:

GIMA

Modello / Model:

Speculum tache - mix / *Vaginal Speculum tache - mix*

Modello / Model:

Speculum vite centrale - mix / *Vaginal Speculum middle screw - mix*

Modello / Model:

Speculum vite laterale - grande / *Vaginal Speculum side screw - large*

Modello / Model:

Speculum vite laterale - medio / *Vaginal Speculum side screw - medium*

Modello / Model:

Speculum vite laterale - mix / *Vaginal Speculum side screw - mix*

Modello / Model:

Speculum vite laterale - piccolo / *Vaginal Speculum side screw - small*

Modello / Model:

Swab plastica sterile / *Sterile plastic swab*

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 7006

Marca / Brandname:

GIMA

Modello / Model:

Proctoscopio adulti / *Adult proctoscope*

Modello / Model:

Proctoscopio pediatrico / *Pediatric proctoscope*

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Dispositivi per aerosolterapia / Nebulizer therapy devices

Classe di rischio / Risk class:
II a

Codice NANDO / NANDO codes:
MD 1102

Marca / Brandname:
AKOD PHARMA

Modello / Model:
AEROSOL A PISTONE

Modello / Model:
AEROSOL AD ULTRASUONI

Marca / Brandname:
GIMA

Modello / Model:
AEROSOL MISTRAL

Modello / Model:
AEROSOL A PISTONE

Modello / Model:
AEROSOL A PISTONE CORSIA

Modello / Model:
AEROSOL A PISTONE EOLO

Modello / Model:
AEROSOL AD ULTRASUONI

Certificate

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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di Kiwa Italia Holding Srl
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Tel +39.051.459.3.111
Fax +39.051.763.382
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www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi



CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	20
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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della saturazione di O2 / *Oxygen saturation measuring devices*

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302

Marca / Brandname:

GIMA

Modello / Model:

PULSOSSIMETRO / *PULSE OXIMETER*

Tipologia / Medical Devices:

Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302

Marca / Brandname:

ACRAF

Modello / Model:

Termometri clinici digitali -Termometro digitale classico Farmamed / *Classic digital Farmamed thermometer*

Modello / Model:

Termometri clinici digitali -Termometro digitale Farmamed / *Digital Farmamed thermometer*

Modello / Model:

Termometri clinici digitali -Termometro digitale Linea F flessibile / *Digital linea F thermometer flexible*

Modello / Model:

Termometri clinici digitali -Termometro digitale NUB Farmamed / *NUB Farmamed Digital thermometer*

Modello / Model:

Termometri clinici digitali -Termometro digitale NUB Farmamed Baby / *NUB Farmamed Baby Digital thermometer*

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Marca / Brandname:

ACRAF

Modello / Model:

Termometri ecologici senza mercurio -Termometro ecologico Farmamed / *Farmamed ecologic thermometer*

Modello / Model:

Termometri ecologici senza mercurio -Termometro ecologico linea F / *Linea F ecologic thermometer*

Marca / Brandname:

CARREFOUR GS

Modello / Model:

Termometri clinici digitali -Termometro digitale Carrefour / *Digital Carrefour thermometer*

Modello / Model:

Termometri clinici digitali -Termometro digitale GS / *Digital GS thermometer*

Marca / Brandname:

CRAF

Modello / Model:

Termometri clinici digitali -Termometro digitale classico Linea F / *Classic digital linea F thermometer*

Marca / Brandname:

FederFARMA.co

Modello / Model:

Termometri ecologici senza mercurio -Termometro ecologico Profar / *Profar ecologic thermometer*

Marca / Brandname:

GABBIANO

Modello / Model:

Termometri clinici digitali -Termometro digitale Farmasan / *Farmasan Digital thermometer*

Modello / Model:

Termometri ecologici senza mercurio -Termometro ecologico Farmasan / *Farmasan ecologic thermometer*

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Marca / Brandname:

GIMA

Modello / Model:

Termometri clinici digitali -Termometro digitale / *Digital thermometer*

Modello / Model:

Termometri clinici digitali -Termometro digitale NUB / *NUB Digital thermometer*

Modello / Model:

Termometri ecologici senza mercurio -Termometro ecologico / *Ecologic thermometer*

Marca / Brandname:

PB PHARMA

Modello / Model:

Termometri clinici digitali -Termometro digitale / *Digital GS thermometer*

Marca / Brandname:

QUIDNOVI PHARMA

Modello / Model:

Termometri ecologici senza mercurio -Termometro ecologico TECNICO Eco / *TECNICO Eco ecologic thermometer*

Marca / Brandname:

SSL HEALTHCARE

Modello / Model:

Termometri ecologici senza mercurio -Termometro clinico Realcheck mercury free / *Clinical thermometer Realcheck mercury free*

Marca / Brandname:

T&B

Modello / Model:

Termometri clinici digitali -Termometro digitale 36.2 T&B / *Digital 36.2 T&B thermometer*

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Dispositivi per misurazione / *Measuring devices*

Classe di rischio / Risk class:
II a

Codice NANDO / NANDO codes:
MD 1302

Marca / Brandname:
GIMA

Modello / Model:
Altimetro - Plicometro - Metro per neonati / *Height meter - Skinfold caliper - Baby measuring meter*

Tipologia / Medical Devices:
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Classe di rischio / Risk class:
II a

Codice NANDO / NANDO codes:
MD 1102

Marca / Brandname:
GIMA

Modello / Model:
Cannule di Guedel sterili / *Sterile Guedel airways*

Modello / Model:
Kit pallone silicone adulti / *Silicone resuscitator kit - adult*

Modello / Model:
Maschere laringee riutilizzabili / *Reusable laryngeal mask airways*

Modello / Model:
Mascherina per rianimazione CPR / *CPR resuscitator mask*

Modello / Model:
Palloni rianimatori / *Resuscitators*

Modello / Model:
Accessori -Maschere in silicone autoclavabili / *Silicone autoclavable face masks*

Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	20
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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Marca / Brandname:

GIMA

Modello / Model:

Accessori -Maschere in silicone con cuscinetto e cuffia autoclavabili / *Silicone autoclavable cushion face masks*

Modello / Model:

Accessori -Maschere ossigeno / *Oxygen masks*

Modello / Model:

Accessori -Mascherine monouso PVC a cuscino d'aria iniettabile / *Disposable PVC injectable air cushion face masks*

Modello / Model:

Accessori -Occhiali ossigeno / *Nasal cannula*

Modello / Model:

Accessori -Tubo ossigeno / *Oxygen tubing*

Modello / Model:

Accessori -Valvola PEEP / *Peep valve*

Tipologia / Medical Devices:

Dispositivi per terapia termica / *Thermic therapy devices*

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1403

Marca / Brandname:

ACRAF

Modello / Model:

Ghiaccio istantaneo monouso Farmamed Gelo Pack / *Farmamed disposable instant ice cold pack*

Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	20
Primo rilascio / First issue date	2006-10-25	Valido da / Valid from	2016-10-24
Scadenza / Valid until	2021-10-24	Ultima modifica / Last change date	2016-11-07

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per terapia termica / *Thermic therapy devices*

Marca / Brandname:

GIMA

Modello / Model:

Ghiaccio istantaneo monouso / *disposable instant ice cold pack*

Modello / Model:

Ghiaccio istantaneo PE / *PE instant ice cold pack*

Modello / Model:

Ghiaccio istantaneo TNT / *TNT instant ice cold pack*

Marca / Brandname:

MENARINI

Modello / Model:

Ghiaccio istantaneo monouso Menarini / *Menarini disposable instant ice cold pack*

Tipologia / Medical Devices:

Elettrocardiografi / *Electrocardiographs*

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302

Marca / Brandname:

GIMA


Modello / Model:

ECG PALMARE

Certificate

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding Srl
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Chief Operating Officer
Giampiero Belcredi



CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	20
Primo rilascio / First issue date	2006-10-25	Valido da / Valid from	2016-10-24
Scadenza / Valid until	2021-10-24	Ultima modifica / Last change date	2016-11-07

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**Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate**

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Sfigmomanometri / Sphygmomanometers

Classe di rischio / Risk class:
II a

Codice NANDO / NANDO codes:
MD 1302

Marca / Brandname:
ACRAF

Modello / Model:
SFIGMO DIGITALE DA POLSO ROSS ANGELINI

Modello / Model:
digitali -SFIGMO DIGITALE DA BRACCIO ROSS ANGELINI

Marca / Brandname:
AKOD PHARMA

Modello / Model:
SFIGMO DIGITALE DA BRACCIO HL AKOD

Modello / Model:
SFIGMO DIGITALE DA POLSO HL AKOD

Modello / Model:
SFIGMO DIGITALE DA TAVOLO HL AKOD

Marca / Brandname:
GIMA

Modello / Model:
a mercurio -STAR

Modello / Model:
a mercurio -YTON

Modello / Model:
a mercurio -YTON PLAUNAZIDE

Modello / Model:
Aneroidi -BOSTON

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CERMET

Chief Operating Officer
Giampiero Belcredi



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Notified Body nr. 0476

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Sfigmomanometri / Sphygmomanometers

Marca / Brandname:

GIMA

Modello / Model:

Aneroidi -BOSTON COMBISARTAN

Modello / Model:

Aneroidi -BOSTON LATEX-FREE

Modello / Model:

Aneroidi -BOSTON LOBIVON

Modello / Model:

Aneroidi -BOSTON VALPRESSION

Modello / Model:

Aneroidi -BOSTON OLPRESS

Modello / Model:

Aneroidi -DALLAS

Modello / Model:

Aneroidi -GIMATONO

Modello / Model:

Aneroidi -LONDON

Modello / Model:

Aneroidi -ROMA

Modello / Model:

Aneroidi -SIRIO

Modello / Model:

Aneroidi -TOKIO

Modello / Model:

Aneroidi -TOKIO ZANTIPRESS

Modello / Model:

Aneroidi -YTON

Chief Operating Officer
Giampiero Belcredi



Organismo Notificato n. 0476

Notified Body nr. 0476

Certificate

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CERMET

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Sfigmomanometri / Sphygmomanometers

Marca / Brandname:

GIMA

Modello / Model:

digitali -AUTOMATICO DA POLSO

Modello / Model:

digitali -24h

Modello / Model:

digitali -AMBULATORIALE

Modello / Model:

digitali -AUTOMATICO DA BRACCIO

Modello / Model:

digitali -DOMINO

Modello / Model:

digitali -SENZA MERCURIO

Modello / Model:

digitali -SFIGMO DIGITALE DA BRACCIO HL GIMA

Modello / Model:

digitali -SFIGMO DIGITALE DA BRACCIO ROSS GIMA

Modello / Model:

digitali -SFIGMO DIGITALE DA POLSO HL GIMA

Modello / Model:

digitali -SFIGMO DIGITALE DA POLSO ROSS GIMA

Modello / Model:

digitali -SFIGMO DIGITALE DA TAVOLO HL GIMA

Modello / Model:

digitali -YTON DIGITALE

Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	20
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La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Certificate

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CERMET

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Giampiero Belcredi

**CE**

Organismo Notificato n. 0476

Notified Body nr. 0476



Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid until	2021-10-14		

Quality Management System Certificate **ISO 13485:2016**

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
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GIMA S.p.A.

Registered Headquarters

- Via Grossi, 2 20121 Milano Italia

Certified Sites

- Via Marconi, 1 20060 Gessate (MI) Italia



SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 0041
PRS N° 089C



GIMA

MOSQUITO FORCEPS - curved - 14 cm

Code: 26873

Category: Forceps

Unit of sale: 1 pc.

Minimum order: 1

Type: Medical device

Class: I

NSIS: 141922

CND: L031306

EAN13: 8023279268737

Description: Stainless Steel haemostatic Mosquito forceps - curved- 14 cm





Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name : HK Greatmade Tech Limited

Manufacturer's Address : 3th, B Building ,BaifuliIndustrial Zone,Shanghenglang village , LongHua town .
Shenzhen City , Guang Dong Province , China

Product : Patient Monitor cable and lead, Class I

Type Designation/Trademark : Patient Monitor cable with leadwires

Product Part No. Of Manufacturer: MC001A-3,MC001B-3, MC001B-5, MC001A-5, MC002A-3, MC002B-3, MC002C-3,MC002D-3, MC003A-5, MC003B-5, MC003C-5, MC003D-5,MC004A-3, MC004B-3, MC005A-5, MC005B-5, MC006A, MC006B, MC007A, MC007B, MC007C, MC007D,MC008, MC009A, MC009B, MC010A,MC010B, MC013-3, MC015-5, MC017A-5, MC017B-5, MC018A-3, MC018B-3,MC019A-3, MC019B-3, MC019C-3,MC019D-3, MC020A-5, MC020B-5, MC020C-5, MC020D-5, MC021A-3,MC021B-3,MC022A-5,MC022B-5,MC023A-3,MC023B-3,MC023C-3,MC023D-3,MC024A-5, MC024B-5,MC024C-5,MC024D-5,MC025A/B/C/D/E/F/G/H-3,MC026A/B/C/D/E/F/G/H-5,MC027-3, MC028-5,MC029A-3,MC029B-3,MC030A-3,MC030B-3,MC031-5,MC032A-5,MC032B-5,MC033A-3, MCD033B-3,MC034A-3,MC034B-3, MC035A-5, MC035B-5,MC036A,MC036B, MC037A-3, MC037B-3, MC038A-5, MC038B-5,MC039-5, MC041A, MC042A-3,MC042B-3, MC043A-5, MC043B-5,MC044-3, MC045,MC046-3,MC046-5,MC047-3,MC047-5 ,MC048-3 ,MC048-5 ,MC049,MC050 ,MC051,MC052A ,MC052B, MC053-3 ,MC053-5,MC054-3 ,MC054-5,MC055 ,MC056, MC057-4AS,MC057-4IS,MC065-3,MC065-5, MC066,MC067,MC068,MC069-3AS/5AS,MC069-3IG/5IG,

Authorized representative established within the EU (if applicable):

Company Name : Prolinx GmbH

Company Address : Brehmstr. 56,40239, Duesseldorf ,Germany

Person responsible for making this declaration

Name, Surname : ZhangHanzhi

Position/Title : Director , Owner

Hereby we declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC




(Place)
(Company stamp and legal signature)

Mar 19th, 2018


(Date)



Compatible Brand	OEM Part No.	Greatmade No.	Description (Cable &Connector)	1-5 pcs	6-19 pcs	Above 20 pcs	
Mindray , CSI ,Datascopelab , BCI , Nellcor		MC026-5TI-SM	3-lead Trunk cable , AHA/IEC , 6pin ,without resistance .Use with MC043-5 leadwire				
Welch Allyn , Critikon		MC026-5TA-SM	3-lead Trunk cable , AHA/IEC , 6pin ,without resistance . Use with MC043-5 leadwire				
See model Compatibilities Below MC026A-5		MC026-3TI-SM	5-lead Trunk cable , AHA/IEC , 6pin ,without resistance . Use with MC042-3 leadwire				
		MC026-3TA-SM	5-lead Trunk cable , AHA/IEC , 6pin ,with 1k resistance . Use with MC042-3 leadwire				



One-piece ECG cable with Leadwires :

Compatible Brand	OEM Part No.	Greatmade No.	Description (Cable &Connector)	1-5 pcs	6-19 pcs	Above 20 pcs	
Mindray , CSI ,Datascopelab , BCI , Nellcor		MC025A-3	One piece ECG cable with 3-ld , TPU, AHA_Snap , 12ft & 120° angle connector.6pin				
Welch Allyn , Critikon		MC025B-3	One piece ECG cable with 3-ld , TPU, AHA_Snap , 12ft & 180° straight connector.6pin				
		MC025C-3	One piece ECG cable with 3-ld , TPU, AHA_Clip , 12ft & 120° angle connector .6pin				
See model Compatibilities Below MC026A-5		MC025D-3	One piece ECG cable with 3-ld , TPU, AHA_Clip , 12ft & 180° straight connector .6pin				
		MC025E-3	One piece ECG cable with 3-ld , TPU, IEC_Snap , 12ft & 120° angle connector.6pin				
		MC025F-3	One piece ECG cable with 3-ld , TPU, IEC_Snap , 12ft & 180° straight connector.6pin				
		MC025G-3	One piece ECG cable with 3-ld , TPU, IEC_Clip , 12ft & 120° angle connector .,6pin				
		MC025H-3	One piece ECG cable with 3-ld , TPU, IEC_Clip , 12ft & 180° straight connector .,6pin				



E



E-77/0S

Connector: RJ11 modular jack

Measuring range: 0-100% O₂

Output signal: 9-13 mV

Response time: < 15 seconds

Warranty: 16 months

Storage: up to 6 months