55

ITALCERT

CERTIFICATO N° 505SGQ03

CERTIFICATE N° 505SGQ03

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

NUOVA APTACA S.r.l.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.
Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.
Commercializzazione di dispositivi medici e diagnostici in vitro.
Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicables
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR
Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2017-10-30	2020-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 023A PRD N° 122B
SGA N° 020D ISP N° 075E
PRS N° 097C
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT

CERTIFICATO N° 505DM05

CERTIFICATE N° 505DM05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

NUOVA APTACA S.r.l.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.
Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.
Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for analysis laboratories. Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana.
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language.

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "GBG-MLD" Nr.4 IDNO 1003600117582 REPUBLICA MOLDOVA, MUN. CHIȘINĂU

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Delibera *Deliberation Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2017-10-30	2019-01-04	2020-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

NUOVA APTACA S.R.L.
Regione Monforte, 30 - Canelli (Asti) ITALY
TEL. +39 0141/83.50.75 - FAX +39 0141/83.52.92
E-mail: info@aptaca.com – http://www.aptaca.com

Certified Company
UNI EN ISO 9001 & UNI CEI EN ISO 13485

Certificate of conformity and quality assurance
Certificato di conformità e di qualità
Certificado de calidad

Esteemed:
Spettabile:
Estimados señores:

I.M. "GBG-MLD" S.R.L
TIGHINA 65 CHISINAU CAP 2001 () MD

Item code Codice Articolo *Código*	Lot number Numero Lotto *Lote*	Expiry date Data di scadenza *Caducidad*	Commercial Invoice n° D.d.t n° *Factura n°*
2120	190725	2024 - 07	/////

Device description / Descrizione Dispositivo / *Descripción*

150ml urine containers in PP, with screw cap not inserted, graduated, Ø58 x 72 mm
Contenitori urina 150ml, in PPtappo a vite a parte, graduatiØ58 x 72 mm

- **We hereby declare that the Device in object is realized and tested in compliance with Quality procedures by controls effected with specific methodologies. Nuova Aptaca Srl have Quality System certified in accordance with UNI EN ISO 9001 and UNI CEI EN ISO 13485 Standards. The Device meets the basic requirements of security and conformity provided by current Regulations and Directives.**
  Si dichiara che il Dispositivo in oggetto è stato realizzato e verificato secondo le procedure di Qualità, con controlli effettuati secondo specifiche metodologie. Nuova Aptaca Srl opera con un Sistema Qualità certificato conforme alle norme UNI EN ISO 9001 e UNI CEI EN ISO 13485. Il Dispositivo risponde ai requisiti essenziali di sicurezza e di conformità previsti dalle Normative e Direttive vigenti.
  Declaramos que los Dispositivo mencionados están fabricados y probado conforme con los procedimientos de Calidad, con controles llevados a cabo de acuerdo con metodologías específicas. Nuova Aptaca Srl funciona con un Sistemas de gestión de la calidad certificado de conformidad con la norma UNI EN ISO 9001 y UNI CEI EN ISO 13485. El dispositivo cumple con los requisitos esenciales de seguridad y cumplimiento por los reglamentos y directivas en vigor.

- **The Device, in its integral package and under appropriate storage conditions, has a expiry date of 5 years from manufacturing date.**
  La validità del Dispositivo, a confezione integra ed in condizioni appropriate di stoccaggio, è stabilita in anni 5 dalla data di fabbricazione.
  La fecha de caducidad del Dispositivo, con el embalaje intacto y en condiciones adecuadas de almacenamiento, se establece en 5 años a partir de la fecha de fabricación.

Certificate date of issue
Data del certificato
Fecha de certificado
02/08/2019

Duilio BUONO
Quality Assurance Manager

48

DECLARATION OF CONFORMITY

Forlì, 19th April 2012

The device named " ECG SUPERGEL" (internal code 10158) has been produced by the company Ceracarta Spa on the basis of the essential requirements,see enclosure I of the directive 93/42/CEE, as prescribed in attachment VII of the above directive.
The writing company Ceracarta located in Via secondo Casadei , 14 Forlì, manufacturer of the product named , " ECG SUPERGEL ", declares under its own responsability that such a device satisfies all the requirements of directive 93/42/CEE as amended by 2007/47/EC , about medical devices and in particular that:

- the Dispositive in object satisfies the essential requirements as in enclosure I of Directive 93/42/CEE;
- the Dispositive in object must be considered as belonging to Class I;
- the Dispositive in object must be esclusively used together with electro-medical instruments for recording, diagnosis and therapy, which base their functioning upon the measuring of energy flows of electric, magnetic and ultrasound type;
- The manufacturer has prepared and keeps the technical files updated in accordance with enclosure VII, section 3 of the directive itself.
- Such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies.

CERACARTA spa
IL PRESIDENTE
Marino Bandini

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

www.imq.it

CERTIFICATO N.
CERTIFICATE N. **9190.CRC3**

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

CERACARTA SPA
VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2008

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori
Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2008 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2017-10-13	2020-10-07

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 9001:2015 entro il 2018/09/14; in caso contrario, il presente certificato cesserà la propria validità in tale data
The Organization shall obtain the certification according to ISO 9001:2015 within 2018/09/14; otherwise the validity of this certificate will expire

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

Data di scadenza del precedente ciclo di certificazione: 2017-10-07
Data di conclusione dell'audit di rinnovo: 2017-10-11
Data della decisione di rinnovo: 2017-10-13

ACCREDIA

IAF: 07, 09, 19, 29

Organismo di Certificazione Federato CISQ
www.imq.it

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

www.cisq.com

IQNet ®

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *as an IQNet Partner hereby states that the organization*

CERACARTA SPA
VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

has implemented and maintains a
Quality Management System
which fulfills the requirements of the following standard

ISO 9001:2008

Issued on: **2017 – 10 – 13**
First issued on: **2002 – 11 – 26**
for the validity date, please refer to the original certificate issued by IMQ*

Registration Number: IT – 112265

IQNet

Alex Stoichitoiu
President of IQNET

CISQ

Ing. Claudio Provetti
President of CISQ

IQNet Partners**:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy* CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Certification *Finland* INTECO *Costa Rica* IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* PCBC *Poland* Quality Austria *Austria* RR *Russia* SIGE *México* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* Vinçotte *Belgium* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document
** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

CSQ
MED
www.imq.it

CISQ is a member of
IQNet
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. **9124.CRC4**

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

EN ISO 13485:2012

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti EN ISO 13485:2012 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2017-10-13	2020-10-07

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 13485:2016 entro il 2019/02/28; in caso contrario, il presente certificato cesserà la propria validità in tale data
The Organization shall obtain the certification according to ISO 13485:2016 within 2019/02/28; otherwise the validity of this certificate will expire

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

Data di scadenza del precedente ciclo di certificazione: 2017-10-07
Data di conclusione dell'audit di rinnovo: 2017-10-11
Data della decisione di rinnovo: 2017-10-13

ACCREDIA

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.

CISQ is the Italian Federation of management system Certification Bodies.

FEDERAZIONE CISQ

www.cisq.com

118 f 134

CERTIFICATE

Reg. Number	10164 - A	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid Until	2021-10-14	IAF Sector	29

Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids

Chief Operating Officer
Giampiero Belcredi

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

This certificate is composed of 1 page.

GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) Italia

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

SQQ N° 007A
SGA N° 010C
PRD N° 069B
PSM N° 004E
PRS N° 089C

CERTIFICATE

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.
Società con socio unico,
soggetta all'attività di direzione e coordinamento di
Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)
Tel +39.051.459.3.111
Fax +39.051.763.362
E-mail: info@kiwacermet.it
www.kiwacermet.it

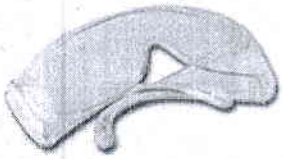
GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) Italia

SGQ N° 007A
SGA N° 010D
PRD N° 069B
PSM N° 004J
PRS N° 089C

POLYSAFE-GOGGLES - bulk

Code:	25661
Category:	Protective goggles and shields
Unit of sale:	1 pc.
Minimum order:	10
Type:	PPE
Class:	I



EAN13:	8023279256611
Description:	They are a vital part of any infectious disease control programme for eye protection. They provide a wide field of vision and excellent optical quality. Designed with top and side shields to protect eyes from every angle. They can fit all head sizes comfortably, and have superior optical clarity. Autoclavable. Norms EN 166.

Honeywell

E.C. Declaration of Conformity

The manufacturer or its legal representative supplier in the European Community:
Honeywell Safety Products Europe

Declares that the Personal Protective Equipment described here after conforms to the provisions of the European Council Directive 89/686/CEE:
Designation: POLYSAFE Clear Polyfort Uncoated Lens
Reference: 1002550
Standard(s): EN166

This PPE is the object of the below EC examination certificate n°:
EC0229

Delivered by:
INSPEC
56 Leslie Hough Way
Salford
M6 6AJ
Greater Manchester
United Kingdom
+44 (0)12 96 68 29 66

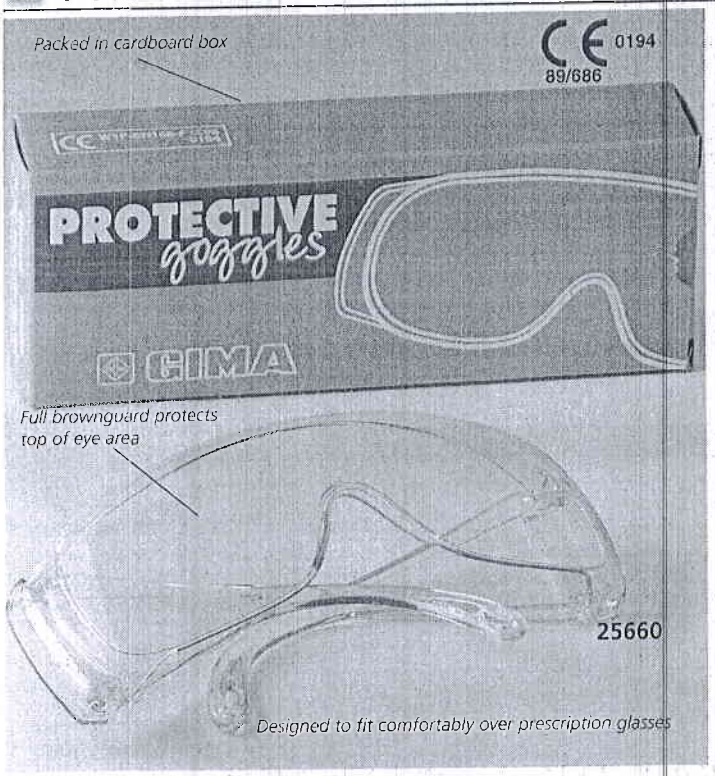
Drawn up in Manchester, on the 17/02/2017
By: K J Warren
Division: Eye and Face Protection

HONEYWELL SAFETY PRODUCTS EUROPE
Immeuble Edison - ZI Paris Nord II - 33 rue des Vanesses
BP 55288 Villepinte - 95958 ROISSY CDG CEDEX
SAS au capital 17 750 000 € - Siret 348 952 307 00137
Tel. +331 4990 7979 - Fax +331 4990 7980

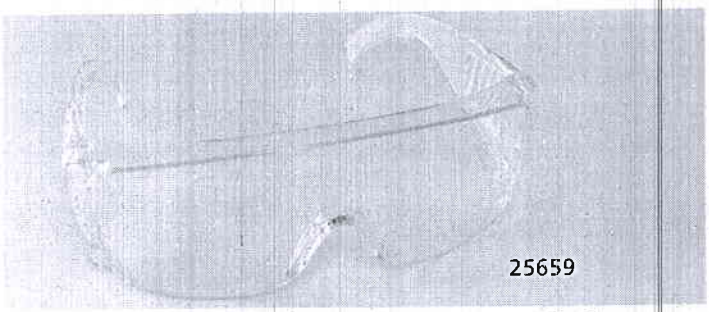
ZI Paris Nord II 33, rue des Vanesses BP 50288 95958 Roissy CDG France
Tel: +33 (0) 49 90 79 79 Fax: +33 (0)1 49 90 79 80
www.honeywellsafety.com

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "GBG-PRIM" IDNO 1003600117562 REPUBLICA MOLDOVA, MUN.

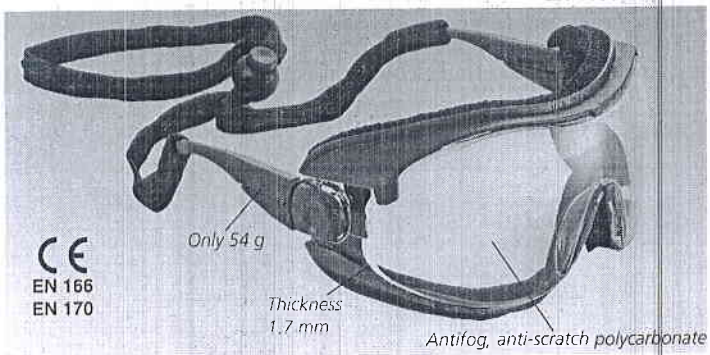
PROTECTIVE GOGGLES



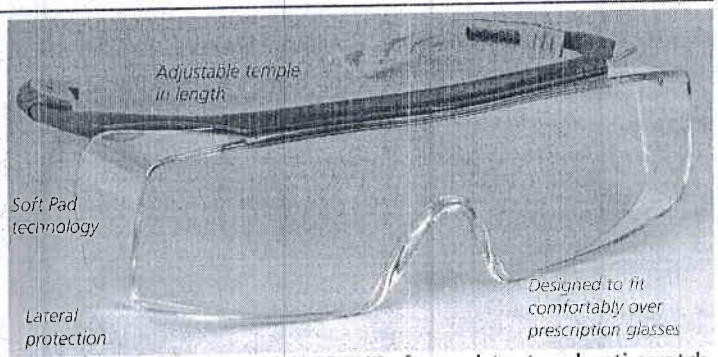
• **25661 POLYSAFE MEDICAL - bulk**
• **25660 POLYSAFE MEDICAL - with box**
They are a vital part of any infectious disease control programme for eye protection. They provide a wide field of vision and excellent optical quality. Designed with top and side shields to protect eyes from every angle. They can fit all head sizes comfortably, and have superior optical clarity. Autoclavable. Norms EN 166.



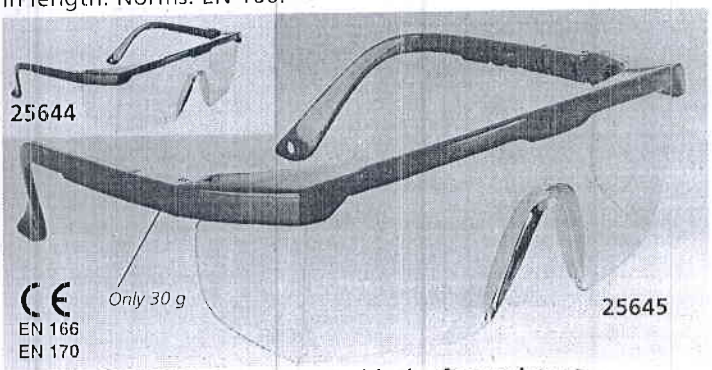
• **25659 GIMASAFE - box of 10 pcs**
Transparent protective goggle.
CE 89/686
EN 166 / EN 170



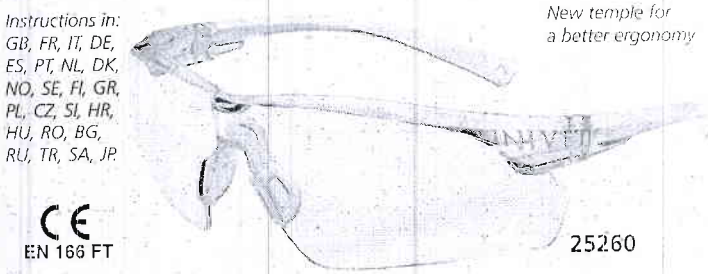
• **25663 HIGH PROTECTION GOGGLES - fog resistant and anti-scratch**
Protection against: droplets and splashes of liquids and high-speed particles at extreme temperature. Lateral protection.
Protection against large dust particles (>0.5 µ).
Protection against optical radiation to standard EN 170.
Resistance to surface damage by fine particles.
Resistance to fogging of oculars.



• **25667 PROTECTIVE GOGGLES 5X7 - fog resistant and anti-scratch**
Superior quality goggles with excellent optical quality, high protection and maximum comfort. Optical quality: Class I.
Protection: protection against high speed particles-low energy and lateral protection. Protection against optical radiations to standard EN 170. Antifog and anti-scratch.
Comfort: ultra light, soft pad technology temples, adjustable in length. Norms: EN 166.



• **25644 SAN DIEGO GOGGLES - black - fog resistant**
• **25645 SAN DIEGO GOGGLES - blue - anti-scratch**
Temple length and inclination adjustment by snap motion.
Protection against high speed particles - low energy and lateral protection. Protection against optical radiation to standard EN 170.



• **25260 505 UP GOGGLES - fog resistant, anti-scratch**
Protection against high speed particles - low energy and lateral protection. Protection against optical radiation to standard EN 170.
- extremely light 24 g only and encircling
- elastic structure, extremely flexible and resistant
- optimal comfort and fit thanks to the soft adjustable nosepad
- neck cord included in the packaging

• **25261 506 UP GOGGLES - green - fog resistant, anti-scratch**
• **25262 506 UP GOGGLES - pink - fog resistant, anti-scratch**
Same as 25260 without neck cord, with below additional features:
- panoramic wrapping lens
- temple regulation in length and inclination
- soft terminal tips to eliminate local pressure

EMERGENCY COVER

Code:	34085
Category:	Emergency blankets
Unit of sale:	1 pc.
Minimum order:	1
Type:	Medical device
Class:	I
NSIS:	363350
CND:	T030399
EAN13:	8023279340853
Description:	Suitable for protection against cold and heat. Silver side in keeps the warmth of the body, gold side out reflects sunbeams.
Technical Specifications:	• Size: 160 x 210 cm • Weight: 67 g

GIMA S.p.A.
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DICHIARAZIONE DI CONFORMITÀ

DECLARATION OF CONFORMITY

La Società GIMA S.P.A., con sede a GESSATE (MI), Via Marconi 1, in qualità di fabbricante dei dispositivi medici:
We undersigned GIMA S.p.A., with head office addressed in Gessate (MI), Via Marconi 1, as the manufacturer of medical devices:

Dispositivi medici / *Medical Devices*	**Codici/Ref. #**
Carrozine e comode *Wheel chairs and comfortable wheel chairs*	27709-27708-27715-27716-27717-27702-27703
Deambulatori *Walkers*	27722-27721-27724
Ausili per disabili (Stampelle, bastoni) *Disabled Aids (Crutches, sticks)*	27780-27781-27782-27793-27798
Aste porta-flebo *Infusion IV stand devices*	27841-27842-27843-27844
Letti *Beds*	27600-27601-27610-27611-27605-27606-27607-27608
Lettini *Little beds*	27500-27501-27510-27502-27505-27506-27507-27401-27402-27404-27405-27407-27406
Barelle *Stretchers*	27850-27800-27801
Carrelli *Trolleys*	27430-27431-27433-27434-27435-27436-27437-27438-27439-27440-27441
Coperte termiche *Thermal blankets*	34085

classe di rischio I (non sterile) in accordo alla regola 1 dell'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii. (recepita in Italia con D.Lgs. 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tali dispositivi:
risk class I non sterile, according to rule 1 of the Annex IX, Directive 93/42/EEC and further amendments (adopted in Italy by Leg. Decree No. 46/97 and further amendments), declare under its own full liability that those devices:

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- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii. come da Fascicolo Tecnico archiviato presso l'azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company
- sono fabbricati in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII del sopra citato decreto legislativo.
  are manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

Gessate, 19/04/2019

GIMA S.p.A.

Il legale Rappresentante

(Nicola Manzoni)

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