CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

Digitally signed by Ceaicovschi Tudor
Date: 2021.08.21 09:55:55 EEST
Reason: MoldSign Signature
Location: Moldova

APTACA S.p.A.

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. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. 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. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). 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 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

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	2020-10-30	2023-10-29

Settore IAF 14 - 29

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

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

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. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). 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

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*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

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

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 510679**

Issued To: **Fiab SpA**
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

In respect of:

The manufacture of sterile and non sterile nasal cannulae, masks, kits and accessories for oxygen and aerosol therapy.
Those aspects of Annex V related to securing and maintaining sterility in the manufacture of femoral compression discs, connection cables, touch-proof plug adaptors, heart wire insulators, electrosurgical pencil holster and cleaning pad for electrosurgical pencil, handle for extraction of permanent intravenous and subcutaneous leads.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2006-10-03** Date: **2019-03-12** Expiry Date: **2021-10-02**

...making excellence a habit.™

CERTIFICATO CE

Certificato n. 1976/MDD

Dichiarazione di approvazione del sistema qualità

(Garanzia di qualità della produzione)

Visto l'esito delle verifiche condotte in conformità all'Allegato V, punto 3 e tenendo conto dell'Allegato VII, punto 5 della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CERACARTA SPA

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

mantiene negli stabilimenti di:

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

un sistema qualità che assicura la conformità dei seguenti prodotti:

Carte per registrazione ad uso medico

Modd. come da documento allegato "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valido solo se provvisto di timbro IMQ.
Marca Ceracarta

ai requisiti metrologici ad essi applicabili della direttiva suddetta (in tutte le fasi della fabbricazione) ed è sottoposta alla sorveglianza prevista dal punto 4 dell'Allegato V.

Riferimento pratiche IMQ:
DM17-0017248-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2017-11-18

Data Scadenza: 2022-11-17

IMQ

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".

EC CERTIFICATE

Certificate No 1976/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V, section 3 and considering the Annex VII, section 5 of the Directive 93/42/EEC and its revised version, we hereby certify that:

CERACARTA SPA

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

manages in the factories of:

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

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

Electromedical recording chart paper

Type ref. as to annexed document "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valid only if provided with IMQ stamp.
Trade mark Ceracarta

with the relevant metrological requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V.

Reference to IMQ files Nos:
DM17-0017248-01.

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: 2017-11-18

Expiry Date: 2022-11-17

IMQ

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

CERACARTA® S.p.A.

Carte diagrammate per tutte le apparecchiature di elettrodiagnostica.
Materiale di consumo ed accessori elettromedicali.
Carte per apparecchi registratori industriali.
Rotoli e pacchi speciali per sistemi esattoriali, di controllo, lotterie.
Etichette radiofrequenza e soluzioni integrate.

Chart Papers for all electrodiagnostic equipment
Disposable and electromedical accessories.
Chart Papers industrial recording instruments.
Special rolls and fanfolds for tickets checking sys
lottery.
Rfid labels and chain solutions.

Sede (Head office and works) :
Via Secondo Casadei, 14 - 47122 FORLI' – ITALY
Tel : 0039 0543 780055 • Fax : 0039 0543 781404
http : // www.ceracarta.it • e-mail : info@ceracarta.it.
Capitale Sociale : € 1.000.000 int. vers.
Registro Imprese FORLI'-CESENA
P.I. / C.F. / VAT.N. IT 00136740404
R.E.A. FORLI' N. 72646 – N. MECC. FO 006863

ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017

Codice famiglia identificativo	Descrizione famiglia
22.01	Pacchi stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
21.01	Rotoli stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
32.01	Schede e dischi stampati medicali

2017-11-18

CSQ

www.imq.it

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.

CERTIFICATO N. / *CERTIFICATE N.* 0967.2019

SI CERTIFICA CHE IL SISTEMA DI GESTIONE AMBIENTALE DI
WE HEREBY CERTIFY THAT THE ENVIRONMENTAL MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

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

SITI / *SITES*

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

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

ISO 14001:2015

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 tramite processo di stampaggio. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radiofrequenza (RFID) tramite processo di stampaggio. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche canto terzi tramite processo di miscelazione dei vari prodotti chimici ed imbottigliamento. Commercializzazione ed immissione in commercia di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG tramite processi di accoppiamenti delle materie prime e taglio a misura. Gestione della produzione ed immissione in commercia di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties by molding process. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID) by molding process. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties by mixing various chemical products and bottling. 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 through coupled processes of raw materials and cut to size. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters

Certificazione rilasciata in conformità al Regolamento Tecnico ACCREDIA RT-09

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*
	2019-06-05	2019-06-05	2022-06-04

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

IMQ

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGA N° 006 D

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

IAF: 07, 09, 19, 12, 29

I processi riconducibili a settori IAF sottolineati risultano non ancora coperti da accreditamento
Processes related to underlined IAF sectors are not yet covered by accreditation

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CERACARTA SPA

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

has implemented and maintains a

Environmental Management System

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 by molding process. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID) by molding process. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties by mixing various chemical products and bottling. 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 through coupled processes of raw materials and cut to size. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters

which fulfills the requirements of the following standard:

ISO 14001:2015

Issued on: **2019 - 06 - 05**
Expires on: ***2022 - 06 - 04***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 125879

Alex Stoichitoiu
President of IQNET

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 Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

DICHIARAZIONE CE DI CONFORMITÀ in accordo alla Direttiva 93/42/CEE
EC DECLARATION OF CONFORMITY according to 93/42/EEC Directive

(Rif./*Ref.* NQ-04-01)

Vicchio, 23 Dicembre 2019
Vicchio, 23 December 2019

La società FIAB SpA, con sede in via P. Costoli, 4 - 50039 Vicchio (FI),
nella persona dell' Amministratore Delegato Alberto Calabrò,
FIAB SpA having its headquarters at 50039 Vicchio (FI), Via P. Costoli 4,
in the person of Managing Director Alberto Calabrò,

dichiara, sotto la propria responsabilità, che i dispositivi
declares, under its own responsibility, that the devices

maschere per ossigenoterapia a concentrazione media, modelli:
medium concentration masks for oxygen therapy, models:

OS/100, OS/100P, OS/100N, OS/100T, OS/100A-30

inclusi nel Master File MF 101 */ part of Master File MF 101*

sono conformi ai requisiti della Direttiva 93/42/CEE (DLgs. 46/97) e successive modifiche,
comply with the requirements of 93/42/EEC Directive, including amendments,

appartengono alla Classe IIa / *are Class IIa products,*

codice GMDN **35171**,
codice CND **R03010201**,

non contengono sostanze medicinali né elementi di origine animale,
do not contain drug substances or elements of animal origin,

che è stata seguita la procedura per la valutazione della conformità descritta in Allegato V della suddetta direttiva,
that FIAB has followed the conformity assessment procedure described in Annex V of the above-mentioned directive,

come riportato sul certificato CE n°CE 510679 rilasciato da British Standard Institution (O.N. n°2797),
as described in the EC Certificate No.CE 510679 issued by British Standard Institution (N.B. No. 2797),

che sono state seguite le procedure di gestione del sistema di qualità FIAB secondo ISO 13485,
Certificato di Registrazione n°MD 77846 rilasciato da BSI,
that the procedures of FIAB quality system management according to ISO 13485 have been followed,
Certificate of Registration No.MD 77846 issued by BSI,

che sono state applicate, tra le altre, le seguenti norme armonizzate:
that, among the others, the following standards were applied:

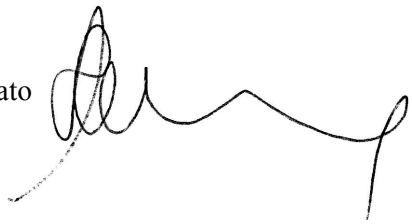
EN ISO 15223-1, 2016 - EN ISO 14971, 2012 - EN ISO 10993-1, 2009 - EN 1041, 2008 - EN ISO 13544-2, 2002+A1:2009 - EN 15986:2011

e che non contengono lattice / *and that they are Latex-free*

CE009/101

Prima emissione/*First Issued:* 18/05/2006
Ultima revisione/*Last Issued:* 23/12/2019

FIAB SpA
Amministratore Delegato
Managing Director
Alberto Calabrò



FIAB SpA – Sede legale: Via P. Costoli, 4 – 50039 VICCHIO – Firenze – Italia
Unità operative: Via Passerini, 2, 4,6 / Via della Resistenza, 18 – 50039 VICCHIO – Firenze – Italia
Tel. +39 0558497999 – FAX +39 0558497979 – www.fiab.it
Cap. Soc. Int. Vers. 500.000 € - C.F.-P.I e n. Reg. Imp. FI 01835220482 – Trib. FI n.33541 – C.C.I.A.A. FI n. 339066 REA – c/c postale 14476501 EUROPEAN VAT: IT 01835220482

EC-Declaration of Conformity

Document number:	EC-OCNFL-100315	1/4
Manufacturer or representative:	OSRAM China Lighting Co. Ltd	
Address:	No.1 North Industrial Road FoShan, GuangDong, P.R.China	
Brand name or trade mark:	OSRAM	
Product type:	Double-capped fluorescent lamp	
Product designation:		
	☒ See attached list	

The designated product(s) is (are) in conformity with the provisions of the following European Directives.

☒	**2006/95/EC** and amendments	**Directive of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits**
☐	**2004/108/EC** and amendments	**Directive of the European Parliament and of the Council of 15 September 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility**
☐	**2000/55/EC** and amendments	**Directive of the European Parliament and of the Council of 18 September 2000 on energy efficiency requirements for ballasts for fluorescent lighting** (to be repealed by 13 April 2010)
☒	**2009/125/EC** and amendments	**Directive of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products**
☐	**244/2009** and amendments	**Commission Regulation (EC) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for non-directional household lamps**
☒	**245/2009** and amendments	**Commission Regulation (EC) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps ...**

Further information regarding compliance with these Directives is given in the **annex** which constitutes a part of this declaration.

Last two digits of the year in which the CE marking was affixed:

Place and date of signatures:

Signatures:

☒ Plant Manager ☐ Product Manager

Quality Manager

Names and contact addresses:

This declaration certifies compliance with the indicated Directives, but implies no warranty of properties.

EC-Declaration of Conformity
Annex

Document number: 2010/01 FS

The conformity of the designated product(s) with the provisions of the European Directive **2006/95/EC** is given by the compliance with the following European Standard(s). If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

☐	**EN 60155:** 1995 + A1:1995 + A2:2007	Glow-starters for fluorescent lamps
☐	**EN 60432-1:** 2000 + A1:2005	Incandescent lamps — Safety specifications — Part 1: Tungsten filament lamps for domestic and similar general lighting purposes
☐	**EN 60432-2:** 2000 + A1:2005	Incandescent lamps — Safety specifications — Part 2: Tungsten filament lamps for domestic and similar general lighting purposes
☐	**EN 60432-3:** 2003 + A1:2005 + A2:2008	Incandescent lamps — Safety specifications — Part 3: Tungsten halogen lamps (non-vehicle)
☐	**EN 60598-1:** 2008	Luminaires — Part 1: General requirements and tests
☐	**EN 60598-2-1:** 1989	Luminaires — Part 2-1: Particular requirements — Fixed general purpose luminaires
☐	**EN 60598-2-2:** 1996 + A1:1997	Luminaires – Part 2-2: Particular requirements — Recessed luminaires
☐	**EN 60598-2-4:** 1997	Luminaires — Part 2-4: Particular requirements — Portable general purpose luminaires
☐	**EN 60598-2-5:** 1998	Luminaires – Part 2-5: Particular requirements — Floodlights
☐	**EN 60598-2-6:** 1994 + A1:1997	Luminaires — Part 2-6: Particular requirements — Luminaires with built-in transformers for filament lamps
☐	**EN 60598-2-7:** 1989 + A2:1996 + A13:1997	Luminaires — Part 2-7: Particular requirements — Portable luminaires for garden use
☐	**EN 60598-2-8:** 1997+ A1:2000 + A2:2008	Luminaires — Part 2-8 : Particular requirements — Handlamps
☐	**EN 60598-2-10:** 2003	Luminaires — Part 2-10: Particular requirements — Portable luminaires for children
☐	**EN 60598-2-13:** 2006	Luminaires — Part 2-13: Particular requirements — Ground recessed luminaires
☐	**EN 60598-2-20:** 1997 + A1:1998 + A2:2004	Luminaires — Part 2: Particular requirements — Lighting chains
☐	**EN 60968:** 1990 + A1:1993 + A2:1999	Self-ballasted lamps for general lighting services — Safety requirements
☒	**EN 61195:** 1999	Double-capped fluorescent lamps — Safety specifications
☐	**EN 61199:** 1999	Single-capped fluorescent lamps — Safety specifications
☐	**EN 61347-1:** 2008	Lamp controlgear — Part 1: General and safety requirements
☐	**EN 61347-2-2:** 2001 + A1:2006 + A2:2006	Lamp controlgear — Part 2-2: Particular requirements for d. c. or a. c. supplied electronic step-down convertors for filament lamps

☐	**EN 61347-2-3:** 2001+A1:2004 + A2:2006	Lamp controlgear — Part 2-3: Particular requirements for a. c. supplied electronic ballasts for fluorescent lamps
☐	**EN 61347-2-12:** 2005	Lamp controlgear — Part 2-12: Particular requirements for d. c. or a. c. supplied electronic ballasts for discharge lamps (excluding fluorescent lamps)
☐	**EN 61347-2-13:** 2007	Lamp controlgear — Part 2-13: Particular requirements for d. c. or a. c. supplied electronic controlgear for LED modules
☐	**EN 61549:** 2003 + A1:2005	Miscellaneous lamps
☐	**EN 62031:** 2008	LED modules for general lighting — Safety specifications
☐	**EN 62035:** 2000 + A1:2003	Discharge lamps (excluding fluorescent lamps) — Safety specifications
☐	**EN 62471:** 2008	Photobiological safety of lamps and lamp systems NOTE: This is a horizontal standard. It is not applicable where photobiological safety is covered by product standards.
☐	**EN 62560:** XXXX	Self-ballasted LED-lamps for general lighting services by voltage > 50 V — Safety specifecations
☒	**IEC 60081:** **1997+A1:2000+A2:2003+A3:2005**	Double-capped fluorescent lamps - Performance specifications
☐		

The conformity of the designated product(s) with the provisions of the European Directive **2004/108/EC** is given by the compliance with the following European Standard(s). If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

☐	**EN 55015:** 2006 + A1:2007 + A2:2009	Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment
☐	**EN 61000-3-2:** 2006	Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
☐	**EN 61000-3-3:** 1995 + A1:2001 + A2:2005	Electromagnetic compatibility (EMC) — Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subjected to conditional connection
☐	**EN 61547:** 1995 + A1:2000	Equipment for general lighting purposes — EMC immunity requirements
☐		

The conformity of the designated product(s) with the provisions of the European Directive **2000/55/EC** is given by the compliance with the following European Standard(s). If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

☐	**EN 50294:** 1998	Measurement method of total input power of ballast-lamp circuits

EC-Declaration of Conformity
Attached list

Document number: EC-OCNFL-100315

A61924700DC	HNS 15W G13 20X1	OSRAM
A61926100DC	HNS 30W G13 10X1	OSRAM

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

№003749

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.00813

Общество с ограниченной ответственностью «МиниМед»

(наименование лица)

241520, Россия, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д.17А

(юридический адрес лица)

241520, Россия, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д.17А

(фактический адрес лица)

ИНН: 3234007127 **ОГРН: 1023202138332**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «МиниМед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики

Дата регистрации: 19-03-2019

Срок действия до: 18-03-2022

Руководитель органа по сертификации: _____ **В. И. Погодин**

(подпись)

Председатель экспертной комиссии: _____ **Е. Д. Курбатова**

(подпись)

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

Федеральное агентство по техническому регулированию и метрологии

НОПСС

Система добровольной сертификации "НОПСС". РОСС RU.31827.04ЖСН1

Орган по сертификации ООО "Невский Альянс". ОГРН 1147847286960 ИНН 7842525530

www.nopss.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ

выдан

Общество с ограниченной ответственностью «МиниМед»

ИНН 3234007127 / ОГРН 1023202138332

241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д.17А

Подтверждает что система менеджмента качества соответствует требованиям ГОСТ ISO 9001-2015 (ISO 9001:2015)

При осуществлении работ согласно приложению №1 к настоящему сертификату

Сертификат выдан на основании решения экспертной комиссии

от 24.09.2018

Срок действия до 24 сентября 2021

Номер в едином реестре системы С1256

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «НОПСС» РОСС RU.31827.04ЖСН1

Руководитель органа по сертификации: **Подпись** _____ Платонов Б.А.

НОПСС СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ

Настоящий сертификат обязывает организацию поддерживать состояние выполняемых работ в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации СДС "НОПСС" и подтверждаться при прохождении ежегодного инспекционного контроля.

Федеральное агентство по техническому регулированию и метрологии

НОПСС

Система добровольной сертификации "НОПСС". РОСС RU.31827.04ЖСН1

Орган по сертификации ООО "Невский Альянс". ОГРН 1147847286960 ИНН 7842525530

www.nopss.ru

ПРИЛОЖЕНИЕ №1

К сертификату соответствия № С1256

Применительно к видам деятельности :

Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики.

НОПСС

Руководитель органа по сертификации: Подпись _____ Платонов Б.А.

НОПСС СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31701101

Zavet Company Subsidiary

04136, Severo-Syretska St, 3, Kyiv, UKRAINE

ISO 13485:2016

Design, Manufacturing, Sales and Service of Medical Stretchers, Medical Beds, Medical Chairs and Eye Charts

Approves that the Medical Devices Quality Management System implemented for above scope.

First Issue Date	11.07.2017
Issue Date	26.12.2019
Expiry Date	25.12.2022
Revision Date/No	26.12.2019 / 5

IAS ACCREDITED Management Systems Certification Body

Deputy General Manager

The certificate inquiry is made by reading QR Code by mobile devices or providing necessary information on http://public.szutest.com.tr.