

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
164429-2014-AQ-GER-DAkKS

Initial certification date:
20 January 2019

Valid:
20 January 2019 - 19 January 2022

This is to certify that the management system of

Greggersen Gasetechnik GmbH

Bodestraße 27-29, 21031 Hamburg, Germany

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:

Design, construction, manufacture, final inspection, distribution, planning, installation and service of central gas supply systems, outlets, medical gas devices and accessories, autogenous welding and cutting equipment, compressed gas technology

Place and date:
Essen, 17 July 2019



Deutsche
Akkreditierungsstelle
D-ZM-18453-01-00

For the issuing office:
DNV GL - Business Assurance
Schnieringshof 14, 45329 Essen, Germany

Thomas Beck
Management Representative



Certificate

The certification body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

Greggersen Gasetechnik GmbH
Bodestraße 27-29
21031 Hamburg
Germany

has introduced, applies and maintains a quality management system in the area of:

**Design and development, manufacture, final inspection, distribution,
installation, and servicing of**

- **Central gas supply systems**
- **Terminal units**
- **Medical gas devices and accessories**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-06-03
Expiry date: 2021-12-18

Report No.: 0874PS25F
Procedure No.: QS – 0874
Certificate No.: 0874GB445200603

Hamburg, 2020-06-03

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAkkS accredited management systems
certification body

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

Greggersen Gasetechnik GmbH
Bodestraße 27-29
21031 Hamburg
Germany

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-06-03

Expiry date: 2023-12-18

Report No.: 0874PS25F
Process No.: QS – 0874
Certificate No.: 0874GB410200603

Hamburg, 2020-06-03

MEDCERT Certification Body
(Markus Bianchi)

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MEDCERT Identification Number: 0482



Appendix of EC Certificate of Conformity

Process No.: QS – 0874

Certificate No.: 0874GB410200603

List of products / product categories included in the scope of certificate

- **Central gas supply systems**
- **Terminal units**
- **Pressure reducers**
- **Flowmeters**
- **Compressed gas and vacuum regulators**
- **Low pressure hose assemblies**
- **Suction units**
- **Vaporizer and atomizer units**
- **Insufflation units**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15



EG-KONFORMITÄTSERKLÄRUNG

entsprechend Anhang II der Richtlinie 93/42/EWG über Medizinprodukte

EC DECLARATION OF CONFORMITY

according to annex II of the Council Directive 93/42/EEC concerning medical devices

Wir erklären in alleiniger Verantwortung, dass die unten bezeichneten Produkte den einschlägigen Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte entsprechen.

We declare under our sole responsibility that the products mentioned below meet the provisions of the Council Directive 93/42/EEC concerning medical devices.

Entnahmestelle Forano / Levante für medizinische Druckgase und Vakuum
Terminal Unit Forano / Levante for compressed medical gases and vacuum

DIN EN ISO 9170-1:2008

DIN 13260-2:2013

SVENSK STANDARD SS 8752430:2017

BRITISH STANDARD BS 5682:2015

NORME FRANÇAISE NF S 90-116:1988

Carbamed

Klasse/ Class: IIa

Revisionsstand/ revision stand: 2.0

Bei einer nicht bestimmungsgemäßen Verwendung des Produkts oder einer nicht mit uns abgestimmten Änderung verliert diese Erklärung ihre Gültigkeit. Diese Konformitätserklärung ist gültig für oben genannte Produkte, mit Herstellungsdatum bis 18.12.2023 oder bis zur Ausstellung einer revidierten Konformitätserklärung.

In the event of using this product not according with the regulations or modification without our approval this declaration will be rendered invalid. This Declaration of Conformity is valid for above products, with date of manufacture up to 18 December 2023 or a revised declaration is made.

Hamburg 2020-01-23/ T. Greggersen Geschäftsführer/director of company

Ort/Datum/Name

Place/Date/Name

Hersteller:
Manufacturer:

GREGGERSEN Gasetechnik, Germany
Bodestraße 27-29
21031 Hamburg
Germany



EC Certificate of Conformity No.: 0874GB410190712



Benannte Stelle:
notified body:

MedCert GmbH
Pilatuspool 2
20355 Hamburg
Germany

CERTIFICATE

Management system as per

ISO 9001 : 2015

Quality Management Systems-Requirements

In accordance with TÜV HELLAS (TÜV NORD) S.A. procedures, it is hereby certified that

HALCOR
COPPER TUBES DIVISION
OF ELVALHALCOR S.A.
62nd km National Road Athens - Lamia
320 11 Inofyta, Viotia
Hellas

HALCOR

with the sites according to the annex and the subcertificates

applies a management system in line with the above standard for the following scope

- Design, Production and Marketing of Copper Products, Copper Alloys, Zinc and Zinc Alloys, Bare, Coated and Thermally Insulated Tubes from Copper and Copper Alloys, Flat Rolled Products with or without Surface Conditioning in the Form of Strips and Sheets from Copper, Copper Alloys and Zinc, Copper Rod for Electrical Applications
- Insulation Foam Production
- Marketing & Storage of Copper Products

Certificate Registration No. 041 07 0119

Audit Report No. E-0822/2019

Valid from 2019-10-19

Valid until 2022-10-18

Initial certification 2007

3Kala/w

TÜV HELLAS (TÜV NORD) S.A. Certification Body

Athens, 2019-10-18

This certification was conducted in accordance with the TÜV HELLAS (TÜV NORD) S.A. auditing and certification procedures and is subject to regular surveillance audits.



ANNEX

to Certificate Registration No. 041 07 0119
ISO 9001 : 2015
Quality Management Systems-Requirements

HALCOR
COPPER TUBES DIVISION
OF ELVALHALCOR S.A.
62nd km National Road Athens - Lamia
320 11 Inofyta, Viotia
Hellas

HALCOR

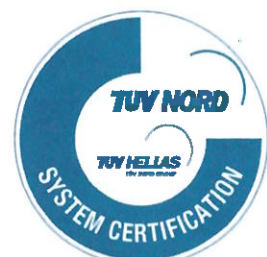
Certificate Registration No.	Site	Scope
041 07 0119-001	COPPER TUBE PLANT 62 nd km Nat. Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	Design, Production and Marketing of Tubes, Bare, Coated and Thermally Insulated Tubes from Copper and Copper Alloys, Flat Rolled Products with or without Surface Conditioning in the Form of Strips and Sheets from Copper, Copper Alloys and Zinc, Copper Rod for Electrical Applications.
041 07 0119-002	FOUNDRY 60 th km Nat. Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	Design and Production of Copper Products, Copper Alloys, Zinc and Zinc Alloys.
041 07 0119-003	ROLLER PRODUCTS PLANT 252, Pireos Str. 177 78 Tavros Hellas	Marketing & Storage of Copper Products.
041 07 0119-004	INSULATION FOAM PLANT 59 th km Nat. Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	Insulation Foam Production

End of the List

3Kala14

TÜV HELLAS (TÜV NORD) S.A. Certification Body

Athens, 2019-10-18



CERTIFICATE

**Management System as per
EN ISO 14001 : 2015**

In accordance with TÜV AUSTRIA procedures, it is hereby certified that

HALCOR

Copper Tubes Division of ELVALHALCOR S.A.

Copper Tube Plant: 62nd km N.R Athens-Lamia, GR-320 11 Inofyta, Viotia, Greece

Foundry: 60th km N.R Athens-Lamia, GR-320 11 Inofyta, Viotia, Greece

Production Line of Cross-Linked Polyethylene Foam Sheets: 59th km N.R Athens-Lamia, GR-320 11 Inofyta, Viotia, Greece

Production of Rolled Products: 252, Piraeus Ave., GR-117 78 Tavros, Athens, Greece

Production line: GR-440 06, Kefalovriso, Ioannina, Greece

Applies an Environmental Management System in line with the above Standard for the following Scope

DESIGN, PRODUCTION AND SALES OF COPPER PRODUCTS, COPPER ALLOYS, ZINC AND ZINC ALLOYS, BARE AND INSULATED TUBES FROM COPPER AND COPPER ALLOYS, FLAT ROLLED PRODUCTS WITH OR WITHOUT SURFACE CONDITIONING IN THE FORM OF STRIPS AND SHEETS FROM COPPER, COPPER ALLOYS AND ZINC, ZINC ALLOYS, COPPER ROD FOR ELECTRICAL APPLICATIONS, STRIPS, SHEETS AND TUBES FROM POLYETHYLENE AND CROSS-LINKED POLYETHYLENE FOAM. DESIGN, PRODUCTION AND TRADE OF COIN BLANKS, DISKS & CUPS FOR CARTRIDGE CASES AND BULLETS.

Certificate Registration No.: **04013030**

Valid until: 2021-09-15

Initial certification: 2013-07-05

Nikolaos Sifakis
Head of Management Systems & Products Certification Division
Certification Body
at TÜV AUSTRIA

Athens, 2018-12-20

This certification was conducted in accordance with TÜV AUSTRIA auditing and certification procedures and is subject to regular surveillance audits.

TÜV AUSTRIA HELLAS
429, Mesogeion Ave.
GR-153 43 Athens, Greece
www.tuvaustriahellas.gr



STEELMET ROMANIA S.A.
 42nd DRUMUL INTRE TARLALE STR.
 032982 BUCHAREST 3rd SECTOR

INSPECTION CERTIFICATE

Type 3.1 acc. EN 10204

Certificate No : 1000401723

DATE: 24.07.2019

Delivery No : 0085191560

Customer	STEELMET ROMANIA S.A.			Cust's Part No	
Cust's Ref No	OR084			Inspection Lot	020000559447
Our Order No	1200099261 / 10	Quantity	2.100,00 MTR		

Designation	CuT m 012,000x1,00x25000 JH HPO M				
according to	EN 12735-1 R220 & EN 13348.				
Material	Cu-DHP				
Chem. Anal.:	CU>99,90-P:0,015-0,040 OK				

Characteristic	Unit of meas.	Specifications	Values	Sample No
ODav	mm	11,960 - 12,040	12,010	1
Smin	mm	>=0,870	0,900	1
Smax	mm	<=1,130	0,940	1
LENGTH	mm	>=25000	25090	1
OVALITY	mm	<=0,84	0,04	1
Rm	N/mm ²	>=220,0	241,3	1
A50	%	>=40,0	49,3	1
EXPANSION	%	>=30,0	OK	1
C TOT. RES. IN.	mg/dm ²	<=0,20	0,07	1
ECT EN 1971	%	100	OK	-

DECLARATION OF CONFORMITY

The products detailed above, conform to the conditions and requirements of the purchaser and to the description, quantities and spec. stated. The Quality Assurance System applied to monitor their production, complies with the requirements of ISO 9001:2015, independently certified by TÜV HELLAS, with certification No 041070119.

Athens

25.07.2019

Q.C. INSPECTOR

Q.A. MANAGER



D. SKARMOUTSOS

ISSUE: C

REV: 2

DATE: DEC. 2017

FORM N3

e-mail: info@halcor.com
 website: www.halcor.com
 VAT number: EL094061318

Offices @ Copper Tube Plant (Mailing Address)
 62nd km Athens-Lamia National Road,
 GR-32011 Inofita-Viotia, GREECE
 Tel.: +30 22620 48111, Fax: +30 22620 48911

Foundry
 60th km Athens-Lamia National Road,
 GR-32011 Inofita-Viotia, GREECE
 Tel.: +30 22620 53479, Fax: +30 22620 53925

Domestic Sales Dept
 252 Pireos str.
 GR-17778, Tavros, Athens, GREECE
 Tel.: +30 210 4898111, Fax: +30 210 4898397

STEELMET ROMANIA S.A.
 42nd DRUMUL INTRE TARLALE STR.
 032982 BUCHAREST 3rd SECTOR

INSPECTION CERTIFICATE
Type 3.1 acc. EN 10204
Certificate No : 1000460516
DATE: 16.12.2020
Delivery No : 0085220657

Customer	STEELMET ROMANIA S.A.			
Cust's Ref No	OR166		Cust's Part No	
Our Order No	1200112596 / 40	Quantity	670,00 MTR	Inspection Lot 020000659807

Designation	CuT m 018,000x1,00x5000 AJ HSH D M			
according to	EN 12735-1 R290, P.E.D 97/23/EC, EN 13348.			
Material	Cu-DHP			
Chem. Anal.:	CU>99,90-P:0,015-0,040		OK	

Characteristic	Unit of meas.	Specifications	Values	Sample No
ODmin	mm	>=17,960	17,980	1
ODmax	mm	<=18,040	18,020	1
ODav	mm	17,960 - 18,040	18,000	1
Smin	mm	>=0,850	0,850	1
Smax	mm	<=1,150	0,890	1
Sav	mm	<=0,894	0,870	1
LENGTH	mm	>=5000	5009	1
WGHT/m	kg/m	<=0,4285	0,4023	1
Rm	N/mm ²	>=290,0	456,6	1
A50	%	>=3,0	5,9	1
EXPANSION	%	>=30,0	OK	1
C TOT. RES. IN.	mg/dm ²	<=0,20	0,10	1
ECT EN 1971	%	100	OK	-

DECLARATION OF COMFORMITY

The products detailed above, conform to the conditions and requirements of the purchaser and to the description, quantities and spec. stated. The Quality Assurance System applied to monitor their production, complies with the requirements of ISO 9001:2015, independently certified by TÜV HELLAS, with certification No 041070119.

Athens

22.12.2020

Q.C. INSPECTOR

Q.A. MANAGER



D. SKARMOUTSOS

ISSUE: C

REV: 2

DATE: DEC. 2017

FORM N3

e-mail: info@halcor.com
 website: www.halcor.com
 VAT number: EL094061318

Offices & Copper Tube Plant (Mailing Address)
 62nd km Athens-Lamia National Road,
 GR-32011 Inofita-Viotia, GREECE
 Tel.: +30 22620 48111, Fax: +30 22620 48911

Foundry
 60th km Athens-Lamia National Road,
 GR-32011 Inofita-Viotia, GREECE
 Tel.: +30 22620 53479, Fax: +30 22620 53925

Domestic Sales Dept
 252 Pireos str.
 GR-17778, Tavros, Athens, GREECE
 Tel.: +30 210 4898111, Fax: +30 210 4898397

STEELMET ROMANIA S.A.
 42nd DRUMUL INTRE TARLALE STR.
 032982 BUCHAREST 3rd SECTOR

INSPECTION CERTIFICATE
Type 3.1 acc. EN 10204
Certificate No : 1000460351
DATE: 18.12.2020
Delivery No : 0085220739

Customer	STEELMET ROMANIA S.A.			
Cust's Ref No	OR166		Cust's Part No	
Our Order No	1200112596 / 50	Quantity	620,00 MTR	Inspection Lot 020000661519

Designation	CuT m 022,000x1,00x5000 AJ HSH D M			
according to	EN 12735-1 R290, P.E.D 97/23/EC, EN 13348.			
Material	Cu-DHP			
Chem. Anal.:	CU>99,90-P:0,015-0,040		OK	

Characteristic	Unit of meas.	Specifications	Values	Sample No
ODmin	mm	>=21,940	21,990	1
ODmax	mm	<=22,060	22,020	1
ODav	mm	21,950 - 22,050	22,005	1
Smin	mm	>=0,850	0,870	1
Smax	mm	<=1,150	0,890 - 0,900	1
Sav	mm	<=0,895	0,880 - 0,885	1
LENGTH	mm	>=5000	5008	1
WGHT/m	kg/m	<=0,5293	0,5224 - 0,5237	1
Rm	N/mm ²	>=290,0	458,5	1
A50	%	>=3,0	6,0	1
EXPANSION	%	>=30,0	OK	1
C TOT. RES. IN.	mg/dm ²	<=0,20	0,07	1
ECT EN 1971	%	100	OK	-

DECLARATION OF COMFORMITY

The products detailed above, conform to the conditions and requirements of the purchaser and to the description, quantities and spec. stated. The Quality Assurance System applied to monitor their production, complies with the requirements of ISO 9001:2015, independently certified by TÜV HELLAS, with certification No 041070119.

Athens

19.12.2020

Q.C. INSPECTOR

Q.A. MANAGER



D. SKARMOUTSOS

FORM N3

ISSUE: C

REV: 2

DATE: DEC. 2017

e-mail: info@halcor.com
 website: www.halcor.com
 VAT number: EL094061318

Offices & Copper Tube Plant (Mailing Address)
 62nd km Athens-Lamia National Road,
 GR-32011 Inofita-Viotia, GREECE
 Tel.: +30 22620 48111, Fax: +30 22620 48911

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 60th km Athens-Lamia National Road,
 GR-32011 Inofita-Viotia, GREECE
 Tel.: +30 22620 53479, Fax: +30 22620 53925

Domestic Sales Dept
 252 Pireos str.
 GR-17778, Tavros, Athens, GREECE
 Tel.: +30 210 4898111, Fax: +30 210 4898397

CERTIFICATE

TÜV NORD Systems GmbH & Co. KG

certifies that the company

**ELVALHALCOR Hellenic Copper and
Aluminium Industry S.A.
HALCOR Copper Tubes Division**

has been verified and recognized as material manufacturer according to

AD 2000-Merkblatt W0

Certificate-No.: 07/203/1326/WP/0890/19

File No.: 1326WL089090 / 8116616079

Production site: **62nd km National Road Athens-Lamia
32011 Oinofyta Viotia, Greece**

The scope of approval is available in the annex scope of approval.

The company fulfils the following essential requirements:

Facilities for appropriate manufacturing and testing, appropriate procedures for manufacturing of the products, qualified personnel for manufacturing and testing of the products and a quality management system with appropriate records, which ensures proper manufacture of the products, as well as compliance with the requirements specified in the material specification.

This certificate is valid until

February 2022

Hamburg, 12.02.2019



Annex: Scope of approval

Profit Center: ISIMK230
Material- and Weldingtechnology
D-22525, Hamburg

Tel: +49-(0)-40-8557-2368
Fax: +49-(0)-40-8557-2710
E-Mail: IMWuS@tuev-nord.de



Liebscher

TÜV NORD Systems GmbH & Co. KG,
Große Bahnstraße 31, D-22525 Hamburg

ZERTIFIKAT

TÜV NORD Systems GmbH & Co. KG

bescheinigt, dass das Unternehmen

**ELVALHALCOR Hellenic Copper and
Aluminium Industry S.A.
HALCOR Copper Tubes Division**

als Werkstoffhersteller gemäß

AD 2000-Merkblatt W0

überprüft und anerkannt wurde.

Zertifikat-Nr.: 07/203/1326/WP/0890/19

Aktenzeichen: 1326WL089090 / 8116616079

Fertigungsstätte: **62nd km National Road Athens-Lamia
32011 Oinofyta Viotia, Griechenland**

Der Geltungsbereich der Überprüfung ist der Anlage Geltungsbereich zu entnehmen.

Die Firma verfügt über folgende Voraussetzungen:

Einrichtungen für ein sachgemäßes Herstellen und Prüfen, geeignete Verfahren zur Herstellung der Erzeugnisse, fachkundiges Personal für das Herstellen und Prüfen der Erzeugnisse sowie ein Qualitätsmanagementsystem mit entsprechenden Aufzeichnungen, das eine sachgemäße Herstellung der Erzeugnisse sowie die Einhaltung der in der Werkstoffspezifikation genannten Anforderungen sicherstellt.

Dieses Zertifikat ist gültig bis

Februar 2022

Hamburg, 12.02.2019



Anlage: Geltungsbereich

Profit Center: ISIMK230
Werkstoff- und Schweißtechnik
D-22525, Hamburg

Tel: +49-(0)-40-8557-2368
Fax: +49-(0)-40-8557-2710
E-Mail: IMWuS@tuev-nord.de



Liebscher

TÜV NORD Systems GmbH & Co. KG,
Große Bahnstraße 31, D-22525 Hamburg

TÜV NORD Systems GmbH & Co. KG

Notifizierte Stelle für Druckgeräte der TÜV NORD Systems GmbH & Co. KG (Reg.-Nr. 0045)

Notified Body for Pressure Equipment Directive (PED), Reg. No. 0045

Geltungsbereich der Überprüfung von Werkstoffherstellern gemäß Druckgeräterichtlinie 2014/68/EU, Anhang I, Nr. 4.3 und AD 2000-Merkblatt W 0
Scope of approval for material manufacturer acc. to Pressure Equipment Directive 2014/68/EU, annex I pt. 4.3 and AD 2000-Guideline W 0

Firma/firm: HALCOR Copper Tubes Division of ELVALHALCOR S.A.

Ort / place: 32011 Oinofyta Viotia, Greece

Anlage zum Zertifikat / Annex to Certificate

DGRL-Nr.: 07/202/1326/WZ/0890/19

AD 2000-W0-Nr.: 07/203/1326/WP/0890/19

Datum / Date: 12.02.2019 / Dr. Fechner

Aktenz. / File: 1326WL089060

SAP: 8116616079

Ifd.Nr. No.	Werkstoffbezeichnung Material Designation	Spezifikation Specification	Lieferzust. Delivery Condition	Erzeugnisform Type of Product	Abmessung / Dimension		Prüfgrundlagen Anforderungen Requirements	Bemerkungen / Remarks
					Dicke [mm] Thickness	Ø [mm] [kg/t]		
1	2	3	4	5	6	7	8	9
1.1	Seamless round copper tube Material Cu-DHP	EN 12735-1/-2	soft, semihard and hard condition	seamless tubes	0.20 to 2.5	4 to 108	Richtlinie 2014/68/EU Directive 2014/68/EU EN 13445-2 EN 13480-2	Zertifiziert gemäß Druckgeräterichtlinie Anhang I, Nr. 4.3 durch die Notifizierte Stelle der TÜV NORD Systems (Reg.-Nr. 0045) Certified acc. to PED annex I, pt. 4.3 by the notified body of TÜV NORD Systems (Reg. no. 0045).
1.2	Seamless round copper tube Material CuFe2P	EN 12735-1	R300	seamless tubes	0.65 to 3.6	9.5 to 54.0		
1.3	Seamless round copper tube Material CuFe2P	EN 12735-1	R420	seamless tubes	0.65 to 0.85	9.5 to 12.7		
2.1	Seamless round copper tube Material Cu-DHP	EN 12735-1/-2	soft and semihard condition	seamless tubes	0.20 to 2.5	4 to 108	AD 2000-W6/2	
2.2	Seamless round copper tube Material Cu-DHP	VaTÜV- Werkstoffblatt 569	gegüht annealed	Seamless round composite tubes from copper and aluminium	0.8 to 1.2	6.35 to 15.87	AD 2000-W6/2, HP 100R	Werkstoffbegutachtung durch Notifizierte Stelle TÜV NORD Systems (Reg. Nr. 0045). Material approval by notified body TÜV NORD Systems (Reg. no. 0045). Az./file no.: 1326W151500

Erklärungen / Explanation:
EN 10027-1:2017, Tab. 18

+AT = Lösungsgeglüht / solution annealed; +N = Normalgeglüht, normalisierend umgeformt / normalized forming;

+NT = Normalgeglüht und angelassen / normalized and tempered; +QT = vergütet / quenched and tempered; +M = Thermomechanisch umgeformt / thermo mechanical forming

+AR = wie gewalzt / as rolled; +SR = Spannungsarmgeglüht / stress relieved; +A = weichgeglüht / soft annealed; +CR = kaltgewalzt / cold rolled

Hinweis zu Werkstoff gem. Richtlinie 2014/68/EU / Hints for materials use acc. to Directive 2014/68/EU:

Für die spezifischen Einsatzbedingungen ist die Zustimmung des Druckgeräteherstellers bzw. der zuständigen benannten Stelle erforderlich.

The specific material operation conditions have to be approved by pressure equipment manufacturer and by the notified body in charge

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

TECHNOLOGIE MEDICALE

101 rue Vaillant Couturier

93130 NOISY-LE-SEC FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Détendeurs et produits pour l'oxygénothérapie et l'aspiration

Pressure regulators and products for oxygen therapy and suction

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P181091-1, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P181091-1, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : February 11th, 2019 (included)

Valable jusqu'au / Expiry date : March 11th, 2022 (included)



On behalf of the President

Béatrice LYS

Technical Director

Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD class</i>
Détendeurs et produits pour l'oxygénothérapie et l'aspiration <i>Pressure regulators and products for oxygen therapy and suction</i>	Switch et Flow-Switch / Switch and Flow-switch Rampe et Dédouleur de prise / Ambulance panel and Y connector Flexible / Hosepipes Robinet direct / Direct valve RTM3 / RTM3 RVTM3 / RVTM3 Soupape de Jeanneret / Water manometer Vanne de vide / Direct vacuum valve Vanne de vide Australie / Direct vacuum valve (Australia) Venturi TM2 / Venturi TM2 Debflo et Debplus / Debflo and Debplus Debson TM2 / Debson TM2 Humidificateur / Humidifier	Ila
	DetregTM / DetregTM Minireg / Minireg RegflowTM / RegflowTM RegsonTM2 / RegsonTM2	Ilb

Identification du site couvert et des activités
Identification of location and activities

TECHNOLOGIE MEDICALE – 101 rue Vaillant Couturier – 93130 NOISY-LE-SEC – FRANCE
Conception, fabrication et contrôle final
Design, manufacture and final control



GMED 0459

On behalf of the President
Béatrice LYS
Technical Director



SERTIKA



LIETUVOS
NACIONALINIS
AKREDITACIJOS
BIURAS

VS SERTIFIKAVIMAS
ISO/IEC 17021

Nr. LA.04.002

CERTIFICATE

Certificate registration No. 18K.1520

6th of November, 2018

The quality management system is designed, implemented and maintained in the

UAB Medical Technologies LBI

Savanoriu av. 271, LT-50131 Kaunas, LITHUANIA

meets the requirements of the standard

ISO 9001:2015

(LST EN ISO 9001:2015)

Scope of certification:

Design, manufacturing and installation of hospital medical supply systems.

This certificate is valid up to 05th of November, 2021.

Director


Ingrida Kusiene





SERTIKA

CERTIFICATE

Certificate registration No. 18M.1521

6th of November, 2018

Medical devices. The quality management system is designed, implemented and maintained in the

UAB Medical Technologies LBI

Savanoriu av. 271, LT-50131 Kaunas, LITHUANIA

meets the requirements of the standard

ISO 13485:2016

(LST EN ISO 13485:2016)

Scope of certification:

Design, manufacturing and installation of hospital medical supply systems.

This certificate is valid up to 05th November, 2021.

Medical devices. The quality management system is certified since 17th of January, 2013.

Director



Ingrida Kusiene