MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000500063-MSC-RvA-DEU

Initial certification date:
22 December 2021

Valid:
22 December 2021 – 21 December 2024

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 and development, manufacture, final inspection, distribution, planning, installation and service of central gas supply systems, terminal units, medical gas devices and accessories, autogenous welding and cutting equipment, compressed gas technology

Place and date:
Barendrecht, 22 December 2021

For the issuing office:
DNV - Business Assurance
Zwolseweg 1, 2994 LB Barendrecht, Netherlands

Erie Koek
Management Representative

MED CERT®

Certification. Medical Only.

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 activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date:	**2021-12-19**
Expiry date:	**2024-12-18**

Report No.:	0874FS27F
Procedure No.:	QS – 0874
Certificate No.:	0874GB445211208

Hamburg, 2021-12-08

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 management systems certification body accredited by DAkkS.

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-19630-04-00

MED CERT®
Certification. Medical Only.

Appendix of certificate

Procedure No.: QS – 0874
Certificate No.: 0874GB445211208

Activities and products/services in the scope of certification

Design and development, manufacte, final inspection, distribution, installation, and servicing of

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

Locations in the scope of certification

Greggersen Gasetechnik GmbH
Bodestraße 27-29
21031 Hamburg
Germany

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 is a management systems certification body accredited by DAkkS.

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

MED CERT®

Certification. Medical Only.

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)

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

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

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

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

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

TÜV HELLAS
TÜV NORD GROUP

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

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.

IAF ΕΣΥΔ MS Certification No of certificate 185

TÜV NORD TÜV HELLAS SYSTEM CERTIFICATION

TÜV HELLAS
TÜV NORD GROUP

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 62nd 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 60th 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 59th km Nat. Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	Insulation Foam Production

End of the List

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

Athens, 2019-10-18

IAF ESYD MS Certification No of certificate 185

TUV NORD TUV HELLAS SYSTEM CERTIFICATION

HALCOR
HELLENIC COPPER INDUSTRY

TÜV HELLAS
TÜV NORD GROUP

Inofyta, 08/02/2019

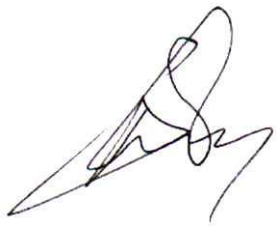
DECLARATION OF CONFORMITY – EN 13348

It is hereby certified that the seamless copper tubes with trade name **TALOS® MED** for medical applications are manufactured by HALCOR/Copper Tubes Division of ELVALHALCOR S.A. at its Inofyta Tube Plant.

TALOS® MED tubes are produced in conformity to the European standard **EN 13348 "Copper and copper alloys, seamless round copper tubes for medical gases or vacuum"** which foresees carbon content less than 0.20 mg/dm^2 and are suitable for the installations used to transfer oxygen, medical compressed air, nitrous oxide and other medical gases.

Product quality is monitored during all manufacturing stages with the application of a Quality Management System complying with the ISO 9001:2015 specification, certified by TUV HELLAS (Cert. No 041070119).

The Quality Assurance Manager



Dr. D. Skarmoutsos

ELVALHALCOR
HELLENIC COPPER AND ALUMINIUM INDUSTRY S.A.

S.A. Register No: 2836/06/B/86/48 Ministry of Economy and Development
General Commercial Registry No: 303401000
VAT No: EL 094061318 Athens S.A. Companies Tax Office
Registered Office: 2-4 Mesogeion Avenue, Athens Tower
2nd Building, Athens GR 11527, GREECE
www.elvalhalcor.com

COPPER TUBES DIVISION:

Offices & Copper Tube Plant
(Mailing Address)
62nd km Athens-Lamia National Road
Oinofyta - Viotia, GR 32011, GREECE
Tel.: +30 22620 48111
Fax: +30 22620 48911
E-mail: info@halcor.com
www.halcor.com

Foundry
60th km Athens-Lamia National Road
Oinofyta - Viotia, GR 32011, GREECE
Tel.: +30 22620 53479, Fax: +30 22620 53925
Domestic Sales Dept
252 Pireos str., Tavros
Athens, GR 17778, GREECE
Tel.: +30 210 4898111, Fax: +30 210 4898397

ELVALHALCOR
HELLENIC COPPER AND ALUMINIUM INDUSTRY S.A.

HALCOR
HELLENIC COPPER INDUSTRY

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

INSPECTION CERTIFICATE
Type 3.1 acc. EN 10204
Certificate No : 1000459465 **DATE:** 08.12.2020
Delivery No : 0085220188

Customer	**STEELMET ROMANIA S.A.**				
Cust's Ref No	**OR166**			Cust's Part No	
Our Order No	**1200112596 / 10**	Quantity	**2.460,00 MTR**	Inspection Lot	**020000659456**

Designation	**CuT m 010,000x1,00x5000 JH 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	>=9,960	10,000	1
ODmax	mm	<=10,040	10,020	1
ODav	mm	9,960 - 10,040	10,010	1
Smin	mm	>=0,870	0,880	1
Smax	mm	<=1,130	0,920	1
Sav	mm	<=0,910	0,900	1
LENGTH	mm	>=5000	5008	1
WGHT/m	kg/m	<=0,2323	0,2293	1
Rm	N/mm²	>=290,0	466,2	1
A50	%	>=3,0	4,8	1
EXPANSION	%	>=30,0	OK	1
C TOT. RES. IN.	mg/dm²	<=0,20	0,12	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 09.12.2020

Q.C. INSPECTOR

HLR 2

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

ELVALHALCOR
HELLENIC COPPER AND ALUMINIUM INDUSTRY S.A.

HALCOR
HELLENIC COPPER INDUSTRY

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

INSPECTION CERTIFICATE
Type 3.1 acc. EN 10204
Certificate No : 1000460344 **DATE:** 18.12.2020
Delivery No : 0085220735

Customer	**STEELMET ROMANIA S.A.**				
Cust's Ref No	**OR166**			Cust's Part No	
Our Order No	**1200112596 / 20**	Quantity	**1.965,00 MTR**	Inspection Lot	**020000660378**

Designation	**CuT m 012,000x1,00x5000 JH 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	>=11,960	11,980	1
ODmax	mm	<=12,040	12,010	1
ODav	mm	11,960 - 12,040	11,995	1
Smin	mm	>=0,870	0,880	1
Smax	mm	<=1,130	0,920	1
Sav	mm	<=0,912	0,900	1
LENGTH	mm	>=5000	5006	1
WGHT/m	kg/m	<=0,2837	0,2807	1
Rm	N/mm²	>=290,0	461,6	1
A50	%	>=3,0	5,3	1
EXPANSION	%	>=30,0	OK	1
C TOT. RES. IN.	mg/dm²	<=0,20	0,12	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

HLR 2

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,
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Tel.: +30 22620 48111, Fax: +30 22620 48911

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252 Pireos str.
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Tel.: +30 210 4898111, Fax: +30 210 4898397

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 28577 rev. 6**
Délivrée à Paris le 02 mars 2020
Issued in Paris on March 2nd, 2020

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, P600892, 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, P600892, 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 :* **March 2nd, 2020 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED SAS GMED SAS
GMED
GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED_b2p3-F-V0-07-2018

GMED - 28577 rev. 6
Renouvelle le certificat 28577-5

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Détendeurs et produits pour l'oxygénothérapie et l'aspiration *Pressure regulators and products for oxygen therapy and suction*	**Switch et Flow-Switch** / *Switch and Flow-switch* **Rampe et Dédoubleur 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*	**IIa**
	DetregTM / *DetregTM* **Minireg** / *Minireg* **RegflowTM** / *RegflowTM* **RegsonTM2** / *RegsonTM2*	**IIb**

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