

UNICERT®



# KALİTE YÖNETİM SİSTEMİ SERTİFİKASI

Universal GmbH  
Belgelendirme Hizmetleri

Bu sertifika,

**Mersin Aym Medikal Gıda Ürünleri Mobilya İnş. San. Ve Tic.  
Ltd. Şti.**

Karaduvar Mah. Dumlupınar Cad. No:244\A Akdeniz / Mersin / Türkiye

kuruluşunun,

**Medikal gaz dağıtım sistemleri, basınçlı medikal gazlar ve anestezi gaz tahliye sistemi uç birimleri, debimetreler, hasta yatak başı ünitesi, yoğun bakım ünitesi, pendant, basınç regülatörü, vakum regülatörü, bölge vana kutusu, alarm paneli tasarım, geliştirme, üretim, kurulum ve servisi**

kapsamında, IA2.007643 sayılı rapordaki inceleme ile

## DIN EN ISO 9001:2015

standardının şartlarına uyan bir kalite yönetim sistemi kurduğunu ve uyguladığını onaylamak üzere verilmiştir.

**Sertifika No : QMS 0817 007643**

**İlk Yayın Tarihi : 2017 - 08 - 24**

**Yayın / Revizyon Tarihi : 2017 - 08 - 24**

**Geçerlilik Tarihi : 2018 - 08 - 23**

**Belge Periyodu : 3 Yıl ( 1.Yıl )**



Deutsche  
Akkreditierungsstelle  
D-ZM-16058-01-00

Universal GmbH



The authenticity of this certificate can be confirmed online or by e-mail to the Head Office via:

UNIVERSAL GmbH • Wilfried-Diekmann-Str. 20b 44536 Lünen Germany • T: +49 (0) 231 9931 9960 • info@uni-cert.de • www.uni-cert.de

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1800524**

Certificate Holder:

**SAXONIA**<sup>®</sup>  
TECHNICAL MATERIALS

**SAXONIA Technical Materials GmbH**  
Rodenbacher Chaussee 4  
63457 Hanau  
Germany

Scope:

Development, manufacturing and sales of contact materials, soldering and brazing alloys, pastes, fluxes and metallurgical specialities

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2018-11-22 until 2021-11-21.

2018-11-22

TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 1800524**

Certificate Holder:

**SAXONIA**<sup>®</sup>  
TECHNICAL MATERIALS

**SAXONIA Technical Materials GmbH**  
Rodenbacher Chaussee 4  
63457 Hanau  
Germany

Scope:

Development, manufacturing and sales of contact materials, soldering and brazing alloys, pastes, fluxes and metallurgical specialities

Proof has been furnished by means of an audit that the requirements of ISO 14001:2015 are met.

Validity:

The certificate is valid from 2018-11-22 until 2021-11-21.

2018-11-22



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# 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](mailto:info@medcert.de).

MEDCERT is a DAkkS accredited management systems  
certification body



Deutsche  
Akkreditierungsstelle  
D-ZM-19630-04-00

# 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](mailto: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](http://www.zlg.de)  
ZLG-BS-237.10.15

## 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](mailto: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](http://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



Benannte Stelle:  
notified body:

MedCert GmbH  
Pilatuspool 2  
20355 Hamburg  
Germany



EC Certificate of Conformity No.: 0874GB410190712

## 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 II DIN für medizinische Druckgase  
und Vakuum**  
***Terminal Unit Forano II DIN for compressed medical gases  
and vacuum***

DIN EN ISO 9170-1 ; DIN 13260-2  
Klasse/ Class IIa  
Revisionsstand/ revision stand 1.4

Bei einer nicht bestimmungsgemäßen Verwendung des Produkts oder einer nicht mit uns abgestimmten Änderung verliert diese Erklärung ihre Gültigkeit.

*In the event of using this product not according with the regulations or modification without our approval this declaration will be rendered invalid.*

Hamburg 2010-07-20/ T. Greggersen Geschäftsführer

Ort/Datum/Name  
Place/Date/Name

**GREGGERSEN**  
**GAsetechnik GmbH**  
Bodestr. 27-29 · 21031 Hamburg  
Tel. 040/73 93 57-0 · Fax 73 93 57-39  
email: [info@greggersen.de](mailto:info@greggersen.de)

Hersteller:  
Manufacturer:

GREGGERSEN Gasetechnik, Germany  
Bodestraße 27-29  
21031 Hamburg  
Germany

 0482

Benannte Stelle:  
notified body:

MedCert GmbH  
Pilatuspool 2  
20355 Hamburg  
Germany



## **CE DECLARATION OF CONFORMITY**

The manufacturer,

**HALCOR S.A., 57<sup>th</sup> Km Nat. Road Athens-Lamia, GR 32011, Inofyta Viotia**

Declare that the seamless, round copper tubes for water and gas in sanitary and heating applications with an outside diameter of 6 x 0,6 mm and 159 x 2,0 mm, for :

- ◆ Distributing networks for hot water and cold water
- ◆ Hot water heating systems including panel heating systems (under-floor, wall, overhead)
- ◆ Domestic gas and liquid fuel distribution
- ◆ Drainage, and disposal of other liquids and gaseous waste
- ◆ Fire suppression and extinction systems
- ◆ Pressure and vacuum systems

comply with the requirements of the following EC Directives, when installed according to notional regulations

**89/106/CEE**            EU Construction Products Directives

**97/23/CE**             EU Pressure Equipment Directive

and comply with the requirements of these directives is demonstrated through conformity with the following standard :

**EN 1057: 2006**      Seamless, round copper tubes for water and gas in sanitary and heating applications

Notified body: Identification No. DPC 0679

### **CSTB**

84, avenue Jean Jaurès  
Champs sur Marne  
F-77447 Marne la Vallée CEDEX 2

Tests Report No. : CA 08-035

M. Danassis, Dipl. Eng., MSc

Quality Manager HALCOR SA - Inofyta

November, 17<sup>th</sup> 2008

## BASIS FOR THE CE MARKING

### **EN 1057: 2006 Annex ZA**

Compliance with the Construction Products Directive 89/106/CEE

<b>Essential caractéristic</b>	<b>Result</b>	<b>Remarks</b>
Reaction to fire	Class A1	Decision of the Commission 96/603/EC, amended 2000/605/EC.
Crushing strength	NPD	Derived from wall thickness and mechanical properties.
Internal pressure	NPD	Derived from wall thickness and mechanical properties.
Dimensional tolérances	Pass	All tubes must meet the specified dimensional tolerances.
Résistance to high temperature	Suitable for use up to 120°C	Temperatures found in heating system pipes have non significant influence on the mechanical properties of copper. Copper tubes can also be used for higher temperatures. National regulations must be observed when used at higher temperatures.
Weldability (for gas network)	Pass	The suitability for welding is characteristic of the copper grade used for products and ensured through the control of the material composition.
Tightness (gas and liquid)	Pass	All tubes must be subjected to leak-tightness testing.
Durability of crushing strength, internal pressure and tightness.	Pass	All tubes must meet the requirements regarding surface condition.

**Note :** NPD : No Performance Determined according to EN 1057 ZA.3

### **EN 1057: 2006 Annex ZB**

Compliance with the Pressure Equipment Directive 97/23/CEE

<b>Essential caractéristic</b>	<b>Remarks</b>
Material properties	Material properties must be meet in accordance with the required mechanical properties. Copper is not susceptible to brittle fracture due to its face-centred cubic crystal structure.
Conformity of material and manufacturer's certified documentation	On request, compliance of the product is confirmed by a certificate of the manufacturer according to EN 10204 Annex ZA.

### **GENERAL REMARKS**

- ◆ The CE marking ensures the free movement of goods within Europe. It does not replace existing national regulations for special applications (e.g. : water, gas, sanitary and heatig installations, etc.)
- ◆ The copper tube is suitable for drinking water applications. The national regulations for drinking water applications remain applicable and must be followed.

# 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.**  
62<sup>nd</sup> 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

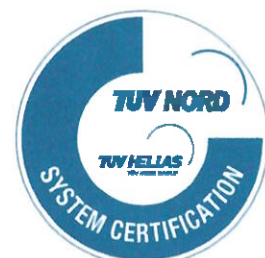
Valid from 2019-10-19  
Valid until 2022-10-18  
Initial certification 2007

*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.**  
62<sup>nd</sup> km National Road Athens - Lamia  
320 11 Inofyta, Viotia  
Hellas

**HALCOR**

Certificate Registration No.	Site	Scope
041 07 0119-001	<b>COPPER TUBE PLANT</b> 62 <sup>nd</sup> km Nat. Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	<b>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.</b>
041 07 0119-002	<b>FOUNDRY</b> 60 <sup>th</sup> km Nat. Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	<b>Design and Production of Copper Products, Copper Alloys, Zinc and Zinc Alloys.</b>
041 07 0119-003	<b>ROLLER PRODUCTS PLANT</b> 252, Pireos Str. 177 78 Tavros Hellas	<b>Marketing &amp; Storage of Copper Products.</b>
041 07 0119-004	<b>INSULATION FOAM PLANT</b> 59 <sup>th</sup> km Nat. Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	<b>Insulation Foam Production</b>

End of the List

*3kala14*

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

Athens, 2019-10-18



# 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: **62<sup>nd</sup> 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: **62<sup>nd</sup> 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



Liebscher

Anlage: Geltungsbereich

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

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

# 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



lfd.Nr No.	Werkstoffbezeichnung Material Designation	Spezifikation Specification	Lieferzust. Delivery Condition	Erzeugnisform Type of Product	Abmessung / Dimension Dicke [mm] Thickness	Ø [mm] [kg/t]	Prüfgrundlagen Anforderungen Requirements	Bemerkungen / Remarks
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	geglüht 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

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

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

+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

# CERTIFICATE

**Quality-Assurance System for material manufacturer  
according to Pressure Equipment Directive 2014/68/EU**

**Certificate no.: 07/202/1326/WZ/0890/19**

**Name and address  
of the manufacturer:**

**ELVALHALCOR Hellenic Copper and Aluminium  
Industry S.A., HALCOR Copper Tubes Division  
62<sup>nd</sup> km National Road Athens-Lamia  
32011 Oinofyta Viotia, Greece**

Herewith we certify that the manufacturer has established and applies a **quality-assurance system related to the material**. This QA System has been subjected to a specific assessment acc. to directive 2014/68/EU, annex I, point 4.3 with regard to the materials mentioned in the scope of approval..

Approved acc. to directive  
2014/68/EU:

**QA-System in relation to materials,  
EN 764-5, section 4.2 and AD 2000-Merkblatt W 0**

Certification file no.:

**1326WL089090**

Audit report file no.:

**8116616079**

Scope of approval:  
(product / material)

**Seamless, round copper tubes**

Production site:

**62<sup>nd</sup> km National Road Athens-Lamia  
32011 Oinofyta Viotia, Greece**

The certificate is valid until:

**February 2022**

Only valid in conjunction with a valid certificate acc. to EN ISO 9001.

**Hamburg, 12.02.2019**



Notified Body (0045)  
for Pressure Equipment

  
Liebscher

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

Annex: scope of approval

Region: ISIMK230  
Werkstoff- und Schweißtechnik  
D-22525, Hamburg

Phone: +49-(0) 40-8557-2368  
Fax +49-(0) 40-8557-2710  
e-mail IMWuS@tuev-nord.de

Member of



CONFÉDÉRATION EUROPÉENNE D'ORGANISMES DE CONTRÔLE

# ZERTIFIKAT

## Qualitätsmanagementsystem für Werkstoffhersteller nach Druckgeräterichtlinie 2014/68/EU

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

Name und Anschrift des  
Herstellers:

ELVALHALCOR Hellenic Copper and Aluminium  
Industry S.A., HALCOR Copper Tubes Division  
62<sup>nd</sup> km National Road Athens-Lamia  
32011 Oinofyta Viotia, Griechenland

Hiermit wird bescheinigt, dass der Hersteller ein **Qualitätsmanagementsystem in Bezug auf Werkstoffe** eingeführt hat und dies anwendet. Dieses QM-System wurde gemäß der Richtlinie 2014/68/EU, Anhang I, Nummer 4.3 in Bezug auf die im Geltungsbereich genannten Werkstoffe einer spezifischen Überprüfung unterzogen.

Geprüft nach Richtlinie 2014/68/EU: **QM-System in Bezug auf Werkstoffe,  
EN 764-5, Abschnitt 4.2 und AD 2000-Merkblatt W 0**

Zertifizierung-Az.: **1326WL089090**

Auditbericht-Nr.: **8116616079**

Geltungsbereich:  
(Produkt / Werkstoff) **Nahtlose Rundrohre aus Kupfer**

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

Das Zertifikat ist gültig bis: **Februar 2022**

Nur gültig in Verbindung mit einem gültigen Zertifikat nach EN ISO 9001.

Hamburg, 12.02.2019



Notifizierte Stelle (0045)  
für Druckgeräte



Liebscher

Anlage: Geltungsbereich

Region: 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

Mitglied der



CONFÉDÉRATION EUROPÉENNE D'ORGANISMES DE CONTRÔLE

# 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

lfd.Nr. No.	Werkstoffbezeichnung Material Designation	Spezifikation Specification	Lieferzust. Delivery Condition	Erzeugnisform Type of Product	Abmessung / Dimension Dicke [mm] Thickness	Ø [mm] [kg/t]	Prüfgrundlagen Requirements	Bemerkungen / Remarks
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	geglüht 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

Erläuterungen / 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



# 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: 62<sup>nd</sup> km N.R Athens-Lamia, GR-320 11 Inofyta, Viotia, Greece

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

Production Line of Cross-Linked Polyethylene Foam Sheets: 59<sup>th</sup> 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](http://www.tuvaustriahellas.gr)



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<sup>2</sup> 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

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

**INSPECTION CERTIFICATE**  
**Type 3.1 acc. EN 10204**

Certificate No : 1000460344  
 Delivery No : 0085220735

DATE: 18.12.2020

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/mm <sup>2</sup>	>=290,0	461,6	1
A50	%	>=3,0	5,3	1
EXPANSION	%	>=30,0	OK	1
C TOT. RES. IN.	mg/dm <sup>2</sup>	<=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



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)**  
 62<sup>nd</sup> km Athens-Lamia National Road,  
 GR-32011 Inofita-Viotia, GREECE  
 Tel.: +30 22620 48111, Fax: +30 22620 48911

**Foundry**  
 60<sup>th</sup> 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 : 1000458611**  
**Delivery No : 0085219784**

**DATE: 30.11.2020**

Customer	<b>STEELMET ROMANIA S.A.</b>		
Cust's Ref No	<b>OR159</b>	Cust's Part No	
Our Order No	<b>1200112168 / 20</b>	Quantity	<b>1.550,00 MTR</b>
		Inspection Lot	<b>020000656623</b>

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

Characteristic	Unit of meas.	Specifications	Values	Sample No
ODav	mm	14,960 - 15,040	15,000 - 15,010	1
Smin	mm	>=0,870	0,880	1
Smax	mm	<=1,130	0,950	1
LENGTH	mm	>=25000	25110	1
OVALITY	mm	<=1,05	0,12 - 0,16	1
Rm	N/mm <sup>2</sup>	>=220,0	242,4	1
A50	%	>=40,0	51,5	1
EXPANSION	%	>=30,0	OK	1
C TOT. RES. IN.	mg/dm <sup>2</sup>	<=0,20	0,08	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

30.11.2020

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)**  
 62<sup>nd</sup> km Athens-Lamia National Road,  
 GR-32011 Inofita-Viotia, GREECE  
 Tel.: +30 22620 48111, Fax: +30 22620 48911

**Foundry**  
 60<sup>th</sup> 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 of Compliance

Certificate Number **120407 - E310015**  
Report Reference **E310015, April 4th, 2007**  
Issue Date **2007 April 12**

Page 1 of 1



**Issued to:** STARQUICK INTERNATIONAL LTD  
C/O UTRECHTSESTRAATWEG 81  
3445 AN WOERDEN THE NETHERLANDS

*This is to certify that representative samples of*


**StarQuick Pipe Clips**  
Types SQ 10, SQ 12, SQ 15, SQ 17, SQ 20, SQ 25, SQ 28, SQ 32, SQ 36,  
SQ 40, SQ 47, SQ 51, SQ 59.

*Have been investigated by Underwriters Laboratories Inc.® (UL) or any authorized licensee of UL in accordance with the Standard(s) indicated on this Certificate.*

**Standard(s) for Safety:** UL 1565 - Positioning Devices  
CSA C22.2 No. 18.5 - Positioning Devices

**Additional Information:** Not Applicable

**Only those products bearing the UL Listing Mark for the US and Canada should be considered as being covered by UL's Listing and Follow-Up Service meeting the appropriate requirements for US and Canada.**

The UL Listing Mark for the US and Canada generally includes: the UL in a circle symbol with "C" and "US" identifiers:  the word "LISTED"; a control number (may be alphanumeric) assigned by UL; and the product category name (product identifier) as indicated in the appropriate UL Directory.

**Look for the UL Listing Mark on the product**

Issued by: *Norma N. Uribe*  
**Norma N. Uribe, Engineer Assoc Proj**

Reviewed by: *James M. Thompson*  
**James M. Thompson, Engineer Sr Staff**

UL International (Netherlands) B.V.

UL International (Netherlands) B.V.

Any information and documentation involving UL Mark services are provided on behalf of Underwriters Laboratories Inc. (UL) or any authorized licensee of UL.  
For questions in Netherlands, you may call +31 0 318 581310.

**Konformitätserklärung des Anbieters  
nach EN ISO/IEC 17050-1  
Declaration of the Provider according  
to EN ISO/IEC 17050-1**



Name und Anschrift des Ausstellers:

Name and address of the exhibitor:

**OBO Bettermann GmbH & Co.KG  
Hüingser Ring 52  
58710 Menden**

Produktbezeichnung: **starQuick-Schelle**

Product designation: **starQuick clip**

Typ: **SQ-10...SQ-59**

Der oben beschriebene Gegenstand der Erklärung ist in der gelieferten Ausführung in Konformität mit den folgenden Dokumenten:

*The above provision of the declaration is delivered in conformity with the following documents:*

**hinterlegten Zeichnungen  
deposited drawings**

Zusätzliche Angaben:  
additional information

**DIN EN ISO 9001:2008  
DIN EN ISO 14001:2008**

Menden, den **23. Januar 2012**

Leitung Innovation & Marketing  
Leader innovation & marketing

Aussteller  
Issuer

Die Sicherheitshinweise der mitgelieferten Produktinformation sowie die allgemeinen Sicherheitsvorschriften sind bei der Montage und im Gebrauch zu beachten.

*Observe the safety instructions of the supplied product information and general local safety regulations as you mount and use the product.*

# CERTIFICATE



## ISO 9001:2015

DEKRA Certification Kft. hereby certifies that the organization

### OBO Bettermann Holding GmbH & Co.KG

#### Scope of certification:

Development, production and sales of

- VBS Connection and fastening systems,
- TBS Transient and lightning protection systems,
- KTS Cable support systems,
- BSS Fire protection systems,
- LFS Cable routing systems,
- EGS Device systems
- UFS Under floor systems.

#### Certified location:

Hüingser Ring 52, 58710 Menden, Germany  
(further locations see annex)

Is a member of the certified body that establishes and maintains a quality management system in accordance with the above mentioned standard.

This was verified by audit report no. W3418H0081/6/6/2.

Certificate registration no.:	370314153/3	Certificate valid from:	25.03.2021
Validity of previous certificate :	14.03.2019	Certificate valid to:	14.03.2022



DEKRA Certification Kft.  
Budapest, 23.03.2021

# Annex to the Certificate No. 370314153/3

valid from 25.03.2021 to 14.03.2022

The following locations belong to the certificate above:

	<b>Headquarter</b>	<b>Certified location</b>	<b>Scope of certification</b>
	OBO Bettermann Holding GmbH & Co.KG	Hüingser Ring 52 D- 58710 Menden	Development, production and sales of - VBS Connection and fastening systems, - TBS Transient and lightning protection systems, - KTS Cable support systems, - BSS Fire protection systems, - LFS Cable routing systems, - EGS Device systems, - UFS Under floor systems
	<b>Subsidiaries</b>	<b>Certified location</b>	<b>Scope of certification</b>
1.	OBO Bettermann Produktion Deutschland GmbH & Co.KG	Bahnhofstraße in Böisperde 92 D- 58708 Menden	Development, production and sales of - LFS Cable routing systems, plastic - powder coating, - logistics (incoming goods, storage, dispatch), - training center
2.	OBO Bettermann Produktion Deutschland GmbH & Co.KG	Fischkuhle 31 D- 58710 Menden	Development, production and sales of - VBS Connection and fastening systems, - TBS Transient and lightning protection systems, - BSS Fire protection systems, - LFS Cable routing systems, steel - logistics (incoming goods, storage, dispatch),
3.	OBTEC GmbH	Hüingser Ring 52 D-58710 Menden	Manufacturing and distribution of fastening elements.
4.	OBO Bettermann Projekt und Systemtechnik GmbH	Langer Brauck 25 D-58640 Iserlohn	Site-related planning, delivery and installation of cable support systems



DEKRA Certification Kft.  
Budapest, 25.03.2021

# CERTIFICATE



## ISO 14001:2015

DEKRA Certification Kft. hereby certifies that the organization

### OBO Bettermann Holding GmbH & Co.KG

#### Scope of certification:

Development, production and sales of

- VBS Connection and fastening systems,
- TBS Transient and lightning protection systems,
- KTS Cable support systems,
- BSS Fire protection systems,
- LFS Cable routing systems,
- EGS Device systems
- UFS Under floor systems

#### Certified location:

Hüingser Ring 52, 58710 Menden, Germany  
(further locations see annex)

has established and maintains an environmental management system according to the above mentioned standard. The conformity was adduced with audit report no. W3418H0081/6/6/2.

Certificate registration no.:	380314153/3	Certificate valid from:	25.03.2021
Validity of previous certificate:	14.03.2019	Certificate valid to:	14.03.2022



DEKRA Certification Kft.  
Budapest, 25.03.2021



# Annex to the Certificate No. 380314153/3

valid from 25.03.2021 to 14.03.2022

The following locations belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	OBO Bettermann Holding GmbH & Co.KG	Hüingser Ring 52 D- 58710 Menden	Development, production and sales of - VBS Connection and fastening systems, - TBS Transient and lightning protection systems, - KTS Cable support systems, - BSS Fire protection systems, - LFS Cable routing systems, - EGS Device systems, - UFS Under floor systems
	Subsidiaries	Certified locations	Scope of certification
1.	OBO Bettermann Produktion Deutschland GmbH & Co.KG	Bahnhofstraße in Böisperde 92 D- 58708 Menden	Development, production and sales of - LFS Cable routing systems, plastic - powder coating, - logistics (incoming goods, storage, dispatch), - training center
2.	OBO Bettermann Produktion Deutschland GmbH & Co.KG	Fischkuhle 31 D- 58710 Menden	Development, production and sales of - VBS Connection and fastening systems, - TBS Transient and lightning protection systems, -BSS Fire Protection systems, - LFS Cable routing systems, steel - logistics (incoming goods, storage, dispatch),
3.	OBTEC GmbH	Hüingser Ring 52 D-58710 Menden	Manufacturing and distribution of fastening elements.
4.	OBO Bettermann Projekt und Systemtechnik GmbH	Langer Brauck 25 D-58640 Iserlohn	Site-related planning, delivery and installation of cable support systems



DEKRA Certification Kft.  
Budapest, 25.03.2021

## **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>
<p>Détendeurs et produits pour l'oxygénothérapie et l'aspiration <i>Pressure regulators and products for oxygen therapy and suction</i></p>	<p>Switch et Flow-Switch / <i>Switch and Flow-switch</i>            Rampe et Dédouleur de prise / <i>Ambulance panel and Y connector</i>            Flexible / <i>Hosepipes</i>            Robinet direct / <i>Direct valve</i>            RTM3 / <i>RTM3</i>            RVTM3 / <i>RVTM3</i>            Soupape de Jeanneret / <i>Water manometer</i>            Vanne de vide / <i>Direct vacuum valve</i>            Vanne de vide Australie / <i>Direct vacuum valve (Australia)</i>            Venturi TM2 / <i>Venturi TM2</i>            Debflo et Debplus / <i>Debflo and Debplus</i>            Debson TM2 / <i>Debson TM2</i>            Humidificateur / <i>Humidifier</i></p>	IIa
	<p>DetregTM / <i>DetregTM</i>            Minireg / <i>Minireg</i>            RegflowTM / <i>RegflowTM</i>            RegsonTM2 / <i>RegsonTM2</i></p>	

**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