

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 2300706**

Certificate Holder:

BRAZETEC® 

BRAZETEC GmbH
Konrad-Zuse-Str. 13
63755 Alzenau
Germany

Scope:

Development, manufacture and sale of solders, solder pastes, fluxes and metallurgical specialty materials

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

Validity:

The certificate is valid from 2024-04-19 until 2027-04-18.

2024-04-23



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln



The German Social Accident Insurance Institution for the Raw Materials and Chemical Industry
(Berufsgenossenschaft Rohstoffe und chemische Industrie - BG RCI) hereby certifies that

BRAZETEC GmbH
Konrad-Zuse-Straße 13
63755 Alzenau

meets the requirements of systematic and effective occupational safety and
health on the basis of the

»Systematic Safety« seal of approval

for the industry-specific implementation of

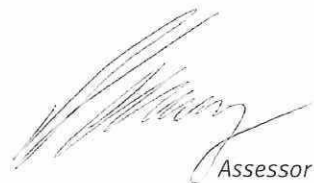
ILO-OSH 2001
guidelines on occupational safety and health management systems
(International Labour Organization).

The investigation on 19th September 2024 was carried out in accordance with
the DGUV procedural principles 311-002 for the assessment of
„occupational safety and health management systems“.

This certificate will remain valid until 18th September 2027.


Prevention manager




Assessor

Heidelberg, 30th September 2024

Registration number RCI/24-024-27-09

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.

Etagenabsperrkasten Ventus für medizinische Druckgase und
Vakuum
valve box Ventus for medical gases and vacuum

DIN EN ISO 7396-1
Klasse/ Class: IIa
Revisionsstand/ revision stand: 1.3

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 08.11.2022 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 08 November 2022 or a revised declaration is made.

Hamburg 2017-11-09/ T. Greggersen Geschäftsführer/director of company

Ort/Datum/Name

Place/Date/Name

Hersteller:

Manufacturer:

GREGGERSEN Gasetechnik, Germany
Bodestraße 27-29
21031 Hamburg
Germany

CE 0482

Benannte Stelle:
notified body:

MedCert GmbH
Pilatuspool 2
20355 Hamburg
Germany



EU Quality Management System Certificate

Certificate no.
2334GB448230918

Final Assessment Report no.
2334AU22F

Effective date
2023-09-18

Expiry date
2028-02-21

This is to certify that the quality system of

Greggersen Service GmbH

Bodestraße 27-29, 21031 Hamburg, Germany

SRN: DE-MF-000025665

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

**The conformity assessment procedure described in Annex IX
Chapter I of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2023-09-18



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

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

Markus Bianchi
Director Certification Body



Certificate no.: [2334GB448230918](#)
Place and date: [Hamburg, 2023-09-18](#)

Sites covered by this certificate

Greggersen Service GmbH, Bodestraße 27-29, 21031 Hamburg, Germany
Greggersen Service GmbH, Bodestraße 34, 21031 Hamburg, Germany
Greggersen Service GmbH, Buchholzer Straße 41, 30629 Hannover, Germany
Greggersen Service GmbH, Industriestraße-West 4, 63808 Haibach, Germany

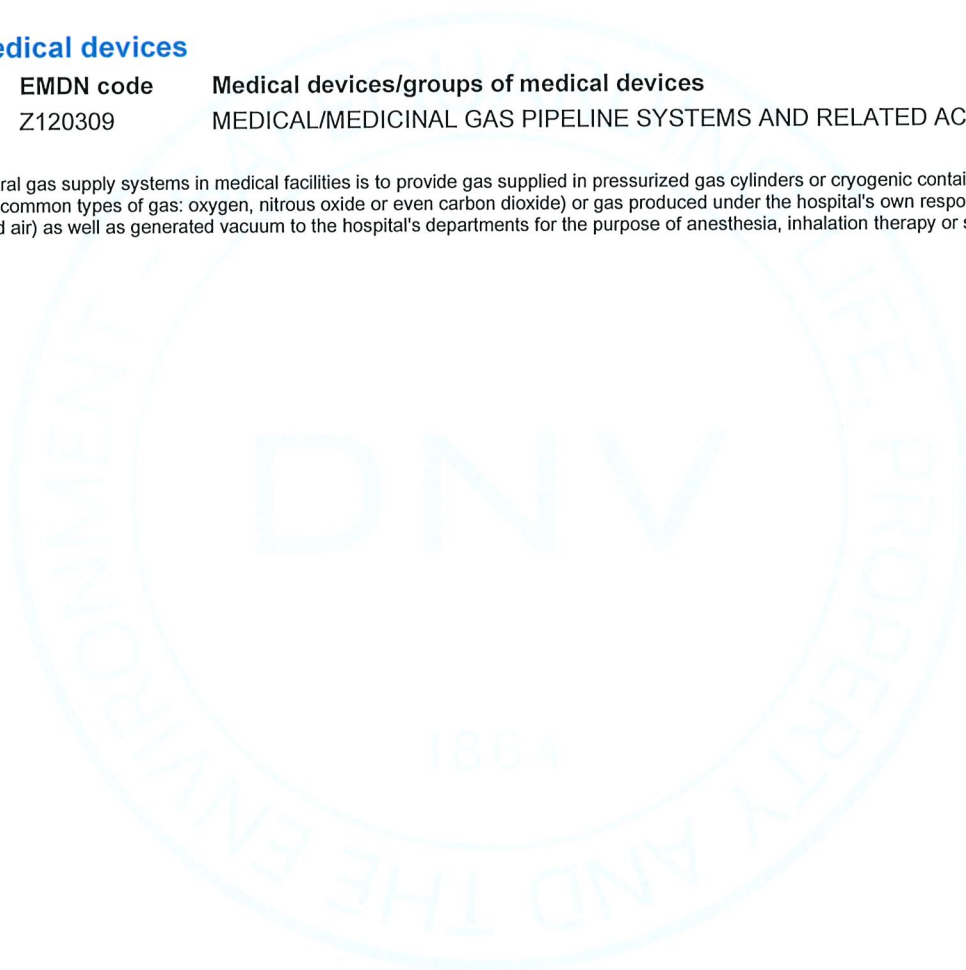
Products covered by this certificate

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0316	Z120309	MEDICAL/MEDICINAL GAS PIPELINE SYSTEMS AND RELATED ACCESSORIES

Intended purpose

The purpose of central gas supply systems in medical facilities is to provide gas supplied in pressurized gas cylinders or cryogenic containers (legal status: medicinal products, common types of gas: oxygen, nitrous oxide or even carbon dioxide) or gas produced under the hospital's own responsibility (mostly medical compressed air) as well as generated vacuum to the hospital's departments for the purpose of anesthesia, inhalation therapy or suction.



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

INSPECTION CERTIFICATE

Type 3.1 acc. EN 10204

Certificate No : 1000569637

DATE: 29.09.2023

Delivery No : 0085284866

Customer	STEELMET ROMANIA S.A.		
Cust's Ref No	OR110SbMacrH		Cust's Part No
Our Order No	1200145338 / 30	Quantity	9.510,00 MTR
		Inspection Lot	020000855817

Designation	CuT m 015,000x1,00x5000 JH HSH D M
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according to	EN 12735-1 R290, PED 2014/68/EU, EN 13348.
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Material	Cu-DHP
Chem. Anal.:	CU>99,90-P:0,015-0,040
	OK

Characteristic	Unit of meas.	Specifications	Values	Sample No
ODmin	mm	>=14,960	14,960 - 14,970	4
ODmax	mm	<=15,040	14,990 - 15,000	4
ODav	mm	14,960 - 15,040	14,980	4
Smin	mm	>=0,870	0,880	4
Smax	mm	<=1,130	0,900 - 0,910	4
Sav	mm	<=0,914	0,890 - 0,895	4
LENGTH	mm	>=5000	5008	4
WGHT/m	kg/m	<=0,3609	0,3510 - 0,3525	4
Rm	N/mm ²	>=290,0	468,0 - 471,2	4
AS0	%	>=3,0	4,8 - 5,8	4
BENDING			OK	4
C TOT. RES. IN.	mg/dm ²	<=0,20	0,07 - 0,08	4
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

30.09.2023

Q.C. INSPECTOR

Q.A. MANAGER



D. SKARMOUTSOS

Tube Plant

WI 8.2.17_Form 8, Rev.: 0

Date: March 2023

ELVALHALCOR HELLENIC COPPER & ALUMINIUM INDUSTRY S.A.
S.A. Register No: 2836/09/Π/06/48
Ministry of Economy & 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

Offices and Copper Tubes Plant
(Mailing Address)
62nd km Athens-Lamia National Road
Oinofyta-Viotia, GR 32011, Greece
T: +30 22620 48111
www.halcor.com

Brass Rods & Tubes Plant
(Mailing Address)
59th km Athens-Lamia
National Road,
Oinofyta-Viotia, GR 32011,
Greece
T: +30 22620 53158

Foundry
60th km Athens-Lamia National Road,
Oinofyta-Viotia, GR 32011, Greece
T: +30 22620 53011
Domestic Sales Dept
Peripheral Unit of West Attica
Municipality of Aspropyrgos
Prati position: Mousaki
Industrial Park Area VIPA VIOPA EM
GR 19300, Greece
T: +30 210 4598111

Certificate

Management system as per

ELOT EN ISO 9001 : 2015

The Certification Body TÜV HELLAS (TÜV NORD) S.A. hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization:

**ELVALHALCOR HELLENIC COPPER AND
ALUMINIUM INDUSTRY S.A.
"ELVALHALCOR S.A."
COPPER AND ALLOYS EXTRUSION DIVISION
62nd km National Road Athens - Lamia
320 11 Inofyta, Viotia
Hellas**

XANKOP

with the locations according to the annex and the Subcertificates

operates a management system in accordance with the requirements of ELOT EN ISO 9001 : 2015 and will be assessed for conformity within the 3 year term of validity of the certificate.

Scope

Design, Manufacture and Sales of:

- **Seamless Bare and Pre - Insulated Tubes, Solid and Hollow Rods, Bars and Profiles, from Copper, Zinc and their Alloys**
- **Strips, Sheets and Discs from Copper Zinc and Alloys, with or without Surface Treatment**
- **Wires from Copper and Aluminium and their Alloys**
- **Wire Mesh from Copper and Iron Alloys**
- **Insulating Sheets, Strips and Tubes from Various Plastic Materials**

Certificate Registration No. 041 07 0119

Audit Report No. E-0822/2023

End of validity of previous certificate: 2022-10-18

Valid from 2022-11-03

Valid until 2025-10-18

Initial certification 2007

Athens, 29.01.2024

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

TÜV HELLAS (TÜV NORD) S.A.

282, Mesogeion Ave.

155 62 Athens, Greece

tuvhellas.gr



Annex

to Certificate Registration No. 041 07 0119

ELOT EN ISO 9001 : 2015

**ELVALHALCOR HELLENIC COPPER AND
ALUMINIUM INDUSTRY S.A.
"ELVALHALCOR S.A."
COPPER AND ALLOYS EXTRUSION DIVISION
62nd km National Road Athens - Lamia
320 11 Inofyta, Viotia
Hellas**



Certificate Registration No.	Location	Scope
041 07 0119-001	COPPER AND ALLOYS EXTRUSION DIVISION COPPER TUBE PLANT 62 nd km National Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	Design, Manufacture and Sales of: Seamless Bare and Pre - Insulated Tubes from Copper, Zinc and their Alloys.
041 07 0119-002	COPPER AND ALLOYS EXTRUSION DIVISION FOUNDRY 60 th km National Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	Design and Production of Copper Products, Zinc and their Alloys.
041 07 0119-003	COPPER AND ALLOYS EXTRUSION DIVISION ROLLER PRODUCTS PLANT 252, Pireos Str. 177 78 Tavros Hellas	Marketing & Storage of Copper Products.

Page 1 of 2

Athens, 29.01.2024



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

TÜV HELLAS (TÜV NORD) S.A.
282, Mesogeion Ave.
155 62 Athens, Greece
tuvhellas.gr



Annex

to Certificate Registration No. 041 07 0119

ELOT EN ISO 9001 : 2015

**ELVALHALCOR HELLENIC COPPER AND
ALUMINIUM INDUSTRY S.A.
"ELVALHALCOR S.A."
COPPER AND ALLOYS EXTRUSION DIVISION
62nd km National Road Athens - Lamia
320 11 Inofyta, Viotia
Hellas**



Certificate Registration No.	Location	Scope
041 07 0119-004	COPPER AND ALLOYS EXTRUSION DIVISION INSULATION FOAM PLANT 59 th km National Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	Design, Manufacture and Sales of Insulating Sheets, Strips and Tubes from Various Plastic Materials.
041 07 0119-005	COPPER AND ALLOYS EXTRUSION DIVISION BRASS RODS AND TUBES PLANT 59 th km National Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	Design, Manufacture and Sales of: - Seamless Bare and Pre - Insulated Tubes, Solid and Hollow Rods, Bars and Profiles, from Copper, Zinc and their Alloys - Strips, Sheets and Discs from Copper Zinc and Alloys, with or without Surface Treatment - Wires from Copper and Aluminium and their Alloys - Wire Mesh from Copper and Iron Alloys

End of the List

Page 2 of 2

Athens, 29.01.2024



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

TÜV HELLAS (TÜV NORD) S.A.
282, Mesogeion Ave.
155 62 Athens, Greece
tuvhellas.gr



CERTIFICATE

Quality management system for material manufacturer
in accordance with the requirements of
Pressure Equipment Directive 2014/68/EU

Certificate No.: **0045/202/1326/WZ/0890/22**

Name and address
of manufacturer: **ELVALHALCOR Hellenic Copper and Aluminium Industry S.A.,
Copper and Alloys Extrusion Division
62nd km National Road Athens-Lamia
Oinofyta Gr 32011 Viotia Greece**

This is to certify that the manufacturer has implemented and applies a **quality management system in relation to materials**. This QM system has been subject to specific verification in accordance with the requirements of Directive 2014/68/EU, Annex I, point 4.3 in relation to the materials. The manufacturer is entitled to issue certificates of specific tests on materials in accordance with the Pressure Equipment Directive and the underlying technical specifications.

Test specification: **EN 764-5, section 4.2 and AD 2000-Merkblatt W 0**

Audit report No.: **SAP-Nr.: 8120325027**

Range of products: **Manufacture of seamless tubes of copper and copper alloys**

Place of manufacture: **62nd km National Road Athens-Lamia
Oinofyta Gr 32011 Viotia Greece**

This certificate is valid until: **May 2025**

Attachment:
scope of approval

Contact:
E-Mail IMWuS@tuev-nord.de
Phone +49-(0)-40-8557-2090



Notified Body 0045 for pressure equipment



Digitally signed by
Liebscher Anne-Kristin
Date: 2022.07.29
11:14:27 +02'00'

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

CERTIFICATE

Certificate No.: 07/203/1326/WP/0890/22

TÜV NORD Systems GmbH & Co. KG certifies that the manufacturer

**ELVALHALCOR Hellenic Copper and Aluminium Industry
S.A., Copper and Alloys Extrusion Division
62nd km National Road Athens-Lamia
Oinofyta Gr 32011 Viotia Greece**

has been verified and recognized as

material manufacturer acc. to AD 2000-Merkblatt W 0

in accordance with the requirements of the certification scheme TNS-AD2000-W0.

Details can be found in the report and the scope of approval.

The manufacturer has the following prerequisites:

- equipment for proper manufacturing and testing,
- suitable procedures for the manufacture of the products,
- skilled personnel for the manufacture and testing of the products, and
- a quality management system with appropriate records that ensures proper manufacture of the products and compliance with the requirements specified in the material specification.

Manufacturing site: See above

Validity: May 2022 until May 2025
Date of issue: 29.07.2022
Audit report No.: SAP-Nr.: 8120325027
Annex: Scope

Digitally signed by
Liebscher Anne-
Kristin



TÜV NORD Systems GmbH & Co. KG
Große Bahnstraße 31, D-22525 Hamburg
Profit Center: ISIMK230
Große Bahnstraße 31
D-22525, Hamburg

Phone: +49-(0)-40-8557-2090
Fax: +49-(0)-40-8557-2710
E-Mail: IMWuS@tuev-nord.de

Inofyta, 08/02/2019

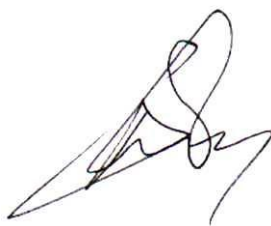
DECLARATION OF CONFORMITY – EN 13348

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/dm² 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

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