

DECLARAȚIE DE CONFORMITATE CE

Noi, (1), declarăm prin prezenta că următoarele produse și variantele acestora respectă următoarele directive și standarde tehnice. Această declarație este valabilă numai pentru produse aflate în starea inițială (cum au fost fabricate). Modificările sau piesele care nu au fost adăugate de producător sunt excluse de sub incidența acestei declarații.

Denumirea produsului	Golire a condensului
Gama de modele	EWD 50, EWD 75, EWD 330, EWD 1500, EWD 16K și variantele acestora
Versiuni de tensiuni	24 V c.c., 24 V c.a., 48 V c.a., 115 V c.a., 230 V c.a.
Directiva 2006/95/CE privind tensiunea joasă	
S-au aplicat standarde armonizate	EN 61010-1:2001 + erata 1:2002
Anul de etichetare CE	99
Dispozitivele cu tensiune operațională de 24 V c.c., 24 V c.a. și 48 V c.a. nu sunt cuprinse în obiectul directivei privind tensiunea joasă.	
Directiva privind EMC 2004/108/CE	
S-au aplicat standarde armonizate	EN 55011:2007 + A2:2007, grupa 1, clasa B; EN 61326-1:2006
Directiva privind echipamentele sub presiune PED 97/23/CE (numai EWD 16K C)	
Clasificarea echipamentelor sub presiune în conformitate cu PED, Articolul 9.	Echipamente sub presiune pentru grupul de lichide 2
Procedură de evaluare a conformității cu respectarea PED, articolul 10.	Modulul A, categoria I

(1): Adresă de contact:

Atlas Copco Airpower n.v.

P.O. Box 100

B-2610 Wilrijk (Antwerp)

Belgium

ATLAS COPCO AIRPOWER
 Naamloze Vennootschap
 B.T.W. 403.992.231
 LUCHTCOMPRESSOREN
 Homsesteenweg 957, WILRIJK
 B 2610 Antwerpen

CS Instruments GmbH

Declaration of Conformity

Consumption counter **VA 420**

CS Instruments GmbH as the manufacturer herewith declares that the above consumption counter complies with the following directives :

Electro-magnetic compliance	2004/108/EG
Low voltage directive	2006/95/EG

For assessing the instrument, the following standards have been referred to:

Electromagnetic compatibility

Emitted interference:	EN 61326-1: 2006-10 + EN 61326-1/Ber.1: 2008-07
Interference resistance:	EN 61326-1: 2006-10 + EN 61326-1/Ber.1: 2008-07

Low voltage derective

Reliability	EN 61010-1: 2002-08 + EN 61010-1/Ber.1:2002-11 + EN 61010-1/Ber.2:2004-01
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Year of first marking with CE label: 09

The product is labeled with the indicated mark



CS Instruments GmbH
Zindelsteiner Str. 15
78052 VS-Tannheim

Phone: +49 (0)7705 978 99-0
Fax: +49 (0)7705 978 99-20

Tannheim, 19. May 2010

A handwritten signature in black ink, appearing to read 'W. Blessing', is written over a horizontal line.

Wolfgang Blessing, Managing Director

CS Instruments GmbH

Declaration of Conformity

for

**DIRECTIVE 2002/96/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27. January 2003
on waste electrical and electronic equipment (WEEE)**

and

**DIRECTIVE 2002/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27. January 2003
on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)**

of the down mentioned instruments from CS Instruments GmbH:

Pressure dew point meter	series FA 4xx and accessories
Flow and consumption meter	series VA 4xx and accessories
Pressure dew point meter	DP 300 and accessories
Leak detector	LD 300 and accessories
Multifunction measuring instrument	DS 300 and accessories
Multi-channel display	DS 300 mobile

CS Instruments GmbH as the manufacturer herewith declares that the above instruments and accessories belongs to the category 9 (WEEE 2002/96/EC). Therefore the above instruments do not fall upward aforementioned directive RoHS 2002/95/EC and are not affected by the material restriction.

In accordance with directive WEEE 2002/96/EC the measuring instruments specified above are taken back from CS Instruments GmbH to the disposal.

CS Instruments GmbH
Zindelsteiner Str. 15
78052 VS-Tannheim
Tel. 07705 978 99-0
Fax 07705 978 99-20

Tannheim, 24. April 2008



Wolfgang Blessing, Geschäftsführer

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
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according to	EN 12735-1 R290, P.E.D 97/23/EC, 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	$\geq 21,940$	21,990	1
ODmax	mm	$\leq 22,060$	22,020	1
ODav	mm	21,950 - 22,050	22,005	1
Smin	mm	$\geq 0,850$	0,870	1
Smax	mm	$\leq 1,150$	0,890 - 0,900	1
Sav	mm	$\leq 0,895$	0,880 - 0,885	1
LENGTH	mm	≥ 5000	5008	1
WGHT/m	kg/m	$\leq 0,5293$	0,5224 - 0,5237	1
Rm	N/mm ²	$\geq 290,0$	458,5	1
A50	%	$\geq 3,0$	6,0	1
EXPANSION	%	$\geq 30,0$	OK	1
C TOT. RES. IN.	mg/dm ²	$\leq 0,20$	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

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 : 1000460452
DATE: 18.12.2020
Delivery No : 0085220736

Customer	STEELMET ROMANIA S.A.			
Cust's Ref No	OR166		Cust's Part No	
Our Order No	1200112596 / 70	Quantity	550,00 MTR	Inspection Lot 020000661599

Designation	CuT m 028,000x1,50x5000 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	>=27,940	27,970	1
ODmax	mm	<=28,060	28,030	1
ODav	mm	27,950 - 28,050	28,000	1
Smin	mm	>=1,275	1,290	1
Smax	mm	<=1,725	1,360	1
Sav	mm	<=1,341	1,325	1
LENGTH	mm	>=5000	5007	1
WGHT/m	kg/m	<=1,0014	0,9905	1
Rm	N/mm ²	>=290,0	451,9	1
A50	%	>=3,0	7,9	1
EXPANSION	%	>=30,0	OK	1
C TOT. RES. IN.	mg/dm ²	<=0,20	0,18	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

21.12.2020

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

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 : 1000461318
DATE: 23.12.2020
Delivery No : 0085221023

Customer	STEELMET ROMANIA S.A.			
Cust's Ref No	OR158		Cust's Part No	
Our Order No	1200112161 / 60	Quantity	300,00 MTR	Inspection Lot 020000659367

Designation	CuT m 035,000x1,50x5000 AJ 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	>=34,930	34,950	1
ODmax	mm	<=35,070	35,060	1
ODav	mm	34,940 - 35,060	35,005	1
Smin	mm	>=1,275	1,280	1
Smax	mm	<=1,725	1,370	1
Sav	mm	<=1,343	1,325	1
LENGTH	mm	>=5000	5023	1
Rm	N/mm ²	>=290,0	457,4	1
A50	%	>=3,0	3,8	1
EXPANSION	%	>=30,0	OK	1
C TOT. RES. IN.	mg/dm ²	<=0,20	0,12	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

02.01.2021

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

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

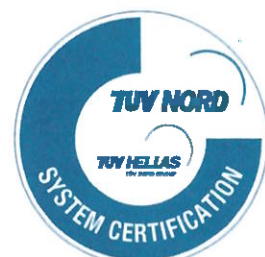
Certificate Registration No.	Site	Scope
041 07 0119-001	COPPER TUBE PLANT 62 nd km Nat. Road Athens - Lamia 320 11 Inofyta, Viotia Hellas	Design, Production and Marketing of Tubes, Bare, Coated and Thermally Insulated Tubes from Copper and Copper Alloys, Flat Rolled Products with or without Surface Conditioning 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

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

Athens, 2019-10-18





CERTIFICATE

TÜV
AUSTRIA

Management System as per ISO 50001 : 2018

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

Cast House: 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

Applies an Energy 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.

Technical Area: Heavy industry

Certificate Registration No.: **011731405290**

Valid until: 2022-12-22

Initial certification: 2017-10-05

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

Athens, 2019-12-23

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



CoPRK429_A5en

Headquarters in Athens bear the responsibility of the Certification decision

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



Inofyta, 08/02/2019

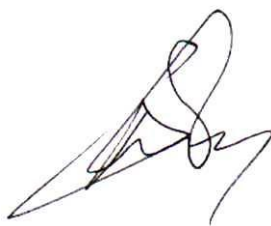
DECLARATION OF CONFORMITY – EN 13348

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

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
62nd 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:

**62nd 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 Druckgeräte richtlinie 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
62nd 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: **62nd 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

Datum / Date: 12.02.2019 / Dr. Fechner
Aktenz. / File: 1326WL089060
SAP: 8116616079

DGRL-Nr.: 07/202/1326/WZ/0890/19
AD 2000-W0-Nr.: 07/203/1326/WP/0890/19

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 Doc.: STW-ZE-AD2000 W0_PED_Geltungsbereich-FB-320_ DE-ENG rev. 02/11.17
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	VdTÜV- 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, T.b. 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



FACTORY CALIBRATION CERTIFICATE

Instrument Type:	Microx	Order Ref:	
Ntron Part No:	02-405	Operator:	A O'Connell
Analyser S/N:	108844	QA:	M. Walsh
Sensor S/N:	360732	Cal. Date:	10-7-14
		Cal Standard:	Certified Gas

NEW ANALYSER CALIBRATION

Cal Standard Input gas (% or ppm)	Certified Gas Ref	Output Reading	Sensor mV or Analyser Counts	DAC Output @4mA	DAC Output @20mA
20.9%	040005114681			161	819
100ppm	040005134659				
95%	040004688534	95	5.00mV		

Signed (Ntron)	A O'Connell	Date:	10-7-14
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ANALYSER RE-CALIBRATION (IF NEEDED)

Cal Standard Input gas (% or ppm)	Certified Gas Ref	Output Reading	Sensor mV or Analyser Counts	DAC Output @4mA	DAC Output @20mA
95%	BCS01007735				

SEE RELEVANT OPERATION MANUAL FOR FURTHER DEVICE SPECIFICATIONS INFORMATION. GAS AND TEST INSTRUMENTS TRACEABLE TO NATIONAL STANDARDS

Validated by (Signature):	C. Rasmussen	Date:	7/10-2014
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MULLAGHBOY INDUSTRIAL PARK, NAVAN, CO MEATH, IRELAND ☐ PHONE: +353 (46) 9071333 ☐ FAX: +353 (46) 9071331 ☐ E-MAIL: info@ntron.com WEBSITE: www.ntron.com/ntron
DALLAM COURT, DALLAM LANE, WARRINGTON, WA2 7LT, UNITED KINGDOM ☐ PHONE: +44 (161) 930 8690 ☐ FAX: +44 (161) 930 8691 ☐ E-MAIL: info@ntron.com WEBSITE: www.ntron.com/ntron

FESTO Test Report

Type 8000104

Pressure range: 0 ... 10 bar rel
Signal: 4 ... 20 mA
Power supply: 8 ... 30 V
Pin assignment: Ub:1 0V:3
Non-linearity: 0.5% BFSL

Partnumber: 8000104
Test item number: P1106LX8M

Pressure [bar]	Signal [mA]	Error [%]
0.000	4.024	0.15
5.000	12.024	0.15
10.000	19.982	-0.11

Max. Non-linearity: 0.13 %

Manufacturer's Declaration

We,

Parker Hannifin Manufacturing Germany GmbH & Co. KG
Gas Separation and Filtration Division EMEA
Im Teelbruch 118, 45219 Essen, Germany,

herewith declare that for products

Fluid group 1

TGA 104–TGA 108, 16–50 bar

TGH 104–TGH 108, 100 bar

TGE 308, 16 bar

Fluid group 2

TGA 104–TGA 114, 16 bar

TGA 104–TGA 110, 25 bar

TGA 104–TGA 110, 50 bar

TGH 104–TGH 108, 100–350 bar

TGE 308–TGE 314, 16 bar

to which this declaration refers, a marking as per pressure equipment directive 2014/34/EU is not required.

Production is subject to the ZANDER Management System and was subjected to a conformity assessment as per Appendix III, module B.

The modules as per Art.4 No.3 are comprised of pressure devices as per the classification list (remains with the manufacturer).

Monitoring of the quality assurance system as per pressure equipment directive 2014/34/EU occurs by *Lloyd's Register Quality Assurance GmbH, Hamburg* (ID No. 0525).

The following standards were used:

- DIN EN 1127-1
- DIN EN 13463-1
- DIN EN 15198
- EN 60204: 2014-10
- 2014/30/EU

Essen,

19.07.2016



Datum / Date

i. V. Dr. Jürgen Timmler
Leiter Technik und Entwicklung /
Manager Engineering and Development

Declaration of Conformity

We,

Parker Hannifin Manufacturing Germany GmbH & Co. KG
Gas Separation and Filtration Division EMEA
Im Teelbruch 118, 45219 Essen, Germany,

herewith declare that products

TGA 104–TGA 118, 16–50 bar

TGH 104–TGH 118, 100–450 bar

TGS 214–TGS 232, 16–100 bar

TGE 308–TGE 326, 16–100 bar

to which this declaration refers, comply with the **2014/34/EU (ATEX)** guideline and were subjected to the conformity assessment after having been classified in this group.

The products were classified as follows: *CE Ex II 2G*

Archiving of documents as per 2014/34/EU (ATEX) guideline is done by the named institution *EXAM BBG Prüf- und Zertifizier GmbH, Bochum (ID No. 0158)*.

The following products comply with the **pressure equipment directive 2014/68/EU** and were subjected to the conformity assessment as Appendix III, module B.

Fluid group 2		Fluid group 1	
TGA 116–TGA 118	16 bar	TGA 110–TGA 118	16 bar–50 bar
TGA 112–TGA 118	25 bar	TGH 110–TGH 118	100 bar–450 bar
TGA 110–TGA 118	50 bar	TGH 104–TGH 108	250 bar– 350 bar
TGH 110–TGH 118	100 bar–450 bar	TGE 314–TGE 326	16 bar
TGE 316–TGA 326	16 bar	TGS 214–TGS 238	16 bar
TGS 214–TGS 238	16 bar		

The modules as per Art. 4 No. 3 are comprised of pressure devices as per the classification list (remains with the manufacturer). The following EC-Type Examination Certificates are available:

TGA PN 16: *LR DTM 0717120*

TGH PN 450: *LR DTM 0717128*

TGA PN 25–50: *LR DTM 0717121*

TGS PN 16: *LR DTM 0717122*

TGH PN 100–350: *LR DTM 0717124*

TGE PN 16: *LR DTM 0717123*

Monitoring of the quality assurance system as per pressure equipment directive 2014/68/EU occurs by *Lloyd's Register Quality Assurance GmbH, Hamburg (ID No.0525)*.

The following standards and technical specifications apply:

DIN EN 1127-1, DIN EN 13463-1, DIN EN 15198, DIN EN 60204-1:2014-10, 2014/30/EU

Essen,

19.07.2016



Datum / Date

i. V. Dr. Jürgen Timmler

Leiter Technik und Entwicklung /
Manager Engineering and Development

BUREAU VERITAS
Certification



WALKER FILTRATION

4748 PACIFIC AVENUE
ERIE, PA 16506 USA

Bureau Veritas Certification Holding SAS – UK Branch certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

THE MANUFACTURE AND DISTRIBUTION OF COMPRESSED AIR, GAS, VACUUM, AUTOCLAVE AND AIR STERILIZATION FILTERS, COMPRESSED AIR DESICCANT DRYERS AND MOISTURE SEPARATORS FOR INDUSTRIAL AND MEDICAL MARKETS

Original cycle start date: **February 19 2010**

Expiry date of previous cycle: **February 16 2019**

Certification / Recertification Audit date: **December 7 2018**

Certification / Recertification cycle start date: **February 26 2019**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **February 16 2022**

Certificate No. US013026 Version: **1**

Signed on behalf BVCH SAS – UK Branch

Certification body address: **5th Floor, 66 Prescott Street, London E1 8HG, United Kingdom**
Local office: **16800 Greenspoint Park Drive, Suite 300S, Houston, TX 77060**

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organization. To check this certificate validity please call: **+(800) 937-9311**





EC Certificate
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-535

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

İNSPİTAL MEDİKAL TEKNOLOJİ ANONİM ŞİRKETİ

Karaoğlu Mahallesi Karaoğlu Küme Evleri No:745 Gölbaşı/ Ankara, Turkey

Products: Flowmeters, Anaesthetic Gas Scavenging (AGSS) System, Area Gas Control Panels, Pipelines and Stations for Medical Gases, Pipelines and Stations for Vacuum, Patient Bed Head Unit, Pendant Unit, Anaesthetic Gas Scavenging Terminal Unit and Probe, Jacks and Outlet for Compressed Medical Gas, Jacks and Outlet for Vacuum, Pressure Regulator with Flowmeter, Manifold and Line Pressure Regulators, Pressure Regulator, Vacuum Regulator, Surgical Suction Unit, Central Vacuum System, Medical Copper Tubings, Electrosurgical Unit

The products defined at the enclosure which is the part of this certificate and contains four page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5220.03
Date of first issue: 02 August 2018
Date of last issue: 21 April 2021
Revision Number: 02
Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

21 April 2021, Istanbul, Turkey

Enclosure of the EC Certificate:

Page 1/4

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-535, Revision Number: 02

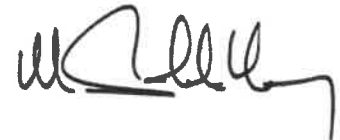
Concerned medical devices;

Product: Flowmeters

Model: FM20.11, FM20.21, FM20.31, FM20.41, FM20.51, FM20.61, FM20.71, FM20.12, FM20.22, FM20.32, FM20.42, FM20.52, FM20.62, FM20.72, FM20.13, FM20.23, FM20.33, FM20.43, FM20.53, FM20.63, FM20.73, FM20.14, FM20.24, FM20.34, FM20.44, FM20.54, FM20.64, FM20.74, FM20.15, FM20.25, FM20.35, FM20.45, FM20.55, FM20.65, FM20.75, FM20.16, FM20.26, FM20.36, FM20.46, FM20.56, FM20.66, FM20.76, FM20.17, FM20.27, FM20.37, FM20.47, FM20.57, FM20.67, FM20.77, FM20.18, FM20.28, FM20.38, FM20.48, FM20.58, FM20.68, FM20.78, FM21.11, FM21.21, FM21.31, FM21.41, FM21.51, FM21.61, FM21.71, FM21.12, FM21.22, FM21.32, FM21.42, FM21.52, FM21.62, FM21.72, FM21.13, FM21.23, FM21.33, FM21.43, FM21.53, FM21.63, FM21.73, FM21.14, FM21.24, FM21.34, FM21.44, FM21.54, FM21.64, FM21.74, FM21.15, FM21.25, FM21.35, FM21.45, FM21.55, FM21.65, FM21.75, FM21.16, FM21.26, FM21.36, FM21.46, FM21.56, FM21.66, FM21.76, FM21.17, FM21.27, FM21.37, FM21.47, FM21.57, FM21.67, FM21.77, FM21.18, FM21.28, FM21.38, FM21.48, FM21.58, FM21.68, FM21.78

Product: Area Gas Control Panels

Model: GZ71.58, GZ71.59, GZ71.60, GZ71.61, GZ71.62, GZ71.63, GZ71.64, GZ71.65, GZ71.66, GZ71.67, GZ71.68, GZ71.69, GZ71.70, GZ71.71, GZ71.72, GZ71.73, GZ71.74, GZ71.75, GZ71.76, GZ71.77, GZ71.78, GZ71.79, GZ71.80, GZ71.81, GZ71.83, GZ71.84, GZ71.85, GZ71.86, GZ71.87, GZ71.88, GZ71.89, GZ71.90, GZ71.91, GZ71.92, GZ71.93



Muhteşem Gökhan Yücel
Head of Notified Body

21 April 2021, Istanbul, Turkey

Enclosure of the EC Certificate:

Page 2/4

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-535, Revision Number: 02

Concerned medical devices;

Product: Pipelines and Stations for Medical Gases

Model: GZ71.01, GZ71.02, GZ71.03, GZ71.04, GZ71.05, GZ71.06, GZ71.07, GZ71.08, GZ71.09, GZ71.10, GZ71.11, GZ71.12, GZ71.13, GZ71.14, GZ71.15, GZ71.16, GZ71.17, GZ71.18

Product: Pipelines and Stations for Vacuum

Model: VK40.02, VK40.03, VK40.04, VK40.05, VK40.06, VK40.07, VK40.08, VK40.09, VK40.10, VK40.11, VK40.12, VK40.13, VK40.14, VK40.15

Product: Anaesthetic Gas Scavenging (AGSS) System

Model: VK50.01, VK50.02, VK50.03, VK50.04

Product: Pendant Unit

Model: FX40.05, FX40.10, FX40.15, FX40.20, FX40.25

Product: Patient Bed Head Unit

Model: GB22.10, GB22.20, GB22.30, GB22.40, GB22.01, GB22.02, GB22.03, GB22.04

Product: Anaesthetic Gas Scavenging Terminal Unit and Probe

Model: PR80.26, PR80.27, PR80.28, PR80.29, PR80.30, PR80.31, JK91.20, JK91.21, JK91.22, JK91.23, JK91.24, JK91.25, JK91.26, JK91.27, JK91.28



Muhteşem Gökhan Yücel
Head of Notified Body

21 April 2021, Istanbul, Turkey



CERTIFICATE

Enclosure of the EC Certificate:

Page 3/4

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-535, Revision Number: 02

Concerned medical devices;

Product: Jacks and Outlet for Compressed Medical Gas

Model: JK90.50, JK90.51, JK90.52, JK90.53, JK90.54, JK90.55, JK90.56, JK90.57, JK90.58, JK90.70, JK90.71, JK90.72, JK90.73, JK90.74, JK90.75, JK90.76, JK90.77, JK90.78, JK90.80, JK90.81, JK90.82, JK90.83, JK90.84, JK90.85, JK90.86, JK90.87, JK90.88, JK90.90, JK90.91, JK90.92, JK90.93, JK90.94, JK90.95, JK90.96, JK90.97, JK90.98, JK91.10, JK91.11, JK91.12, JK91.13, JK91.14, JK91.15, JK91.16, JK91.17, JK91.18, PR80.01, PR80.03, PR80.04, PR80.05, PR80.06, PR80.08, PR80.09, PR80.10, PR80.11, PR80.13, PR80.14, PR80.15, PR80.16, PR80.18, PR80.19, PR80.20, PR80.21, PR80.23, PR80.24, PR80.25, PR82.01, PR82.03, PR82.04, PR82.05, PR82.06, PR82.08, PR82.09, PR82.10, PR82.11, PR82.13, PR82.14, PR82.15, PR82.16, PR82.18, PR82.19, PR82.20, PR82.21, PR82.23, PR82.24, PR82.25

Product: Jacks and Outlet for Vacuum

Model: PR80.02, PR80.07, PR80.12, PR80.17, PR80.22, PR82.02, PR82.07, PR82.12, PR82.17, PR82.22, JK90.60, JK90.61, JK90.62, JK90.63, JK90.64, JK90.65, JK90.66, JK90.67, JK90.68

Product: Manifold and Line Pressure Regulators

Model: GZ71.20, GZ71.21, GZ71.22, GZ71.23, GZ70.10, GZ70.20, GZ70.30, GZ70.40, GZ70.50

Product: Pressure Regulator

Model: FG50.10, FG50.20, FG50.40, FG50.50, FG50.11, FG50.21, FG50.41, FG50.51, FG50.12, FG50.22, FG50.42, FG50.52, FG50.13, FG50.23, FG50.43, FG50.53, FG50.14, FG50.24, FG50.44, FG50.54, FG50.15, FG50.25, FG50.45, FG50.55, FG50.16, FG50.26, FG50.46, FG50.56

Muhteşem Gökhan Yücel
Head of Notified Body

21 April 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

Page 4/4

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-535, Revision Number: 02

Concerned medical devices;

Product: Pressure Regulator with Flowmeter

Model: FM21.85, FM21.86, FM21.87, FM21.88

Product: Vacuum Regulators

Model: FG50.30, FG50.31, FG50.32, FG50.33, FG50.34, FG50.35, FG50.36, FG51.01, FG51.02, FG51.03, FG51.04, FG51.05, FG51.06, FG51.07, FG52.01, FG52.02, FG52.03, FG52.04, FG52.05, FG52.06, FG52.10, FG52.11, FG52.12, FG52.13, FG52.14, FG52.15, FG53.01, FG53.02, FG53.03, FG53.04, FG53.05, FG53.06, FG53.10, FG53.11, FG53.12, FG53.13, FG53.14, FG53.15

Product: Surgical Suction Unit

Model: SU60, SU60.10, SU60.15, SU60.22, SU60.33, SU60.05

Product: Central Vacuum System

Model: AT20.75

Product: Electrosurgical Unit

Model: NS01.60, NS02.00 Touch, NS02.50, NS04.00

Product: Medical Copper Tubings

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



Muhteşem Gökhan Yücel
Head of Notified Body

21 April 2021, Istanbul, Turkey



TRB
INTERNATIONAL

CERTIFICATE

İNSPİTAL MEDİKAL TEKNOLOJİ A.Ş.

KARAOĞLAN MAHALLESİ KARAOĞLAN KÜME EVLERİ NO:745 GÖLBAŞI ANKARA

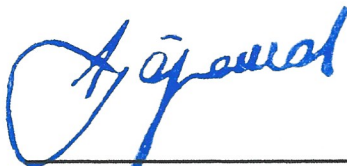
ISO 9001:2015

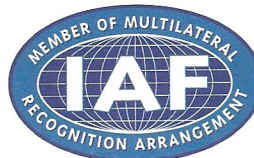
DESIGN, DEVELOPMENT, PRODUCTION, INSTALLATION AND SERVICES OF OPERATION THEATER EQUIPMENTS, INTENSIVE CARE UNIT AND EMERGENCY, MEDICAL SERVICE EQUIPMENTS, PATIENT ROOM AND CLINICAL EQUIPMENTS, STERILIZATION AND STAINLESS STEEL EQUIPMENTS, MEDICAL GAS SYSTEM AND EQUIPMENTS, SUCTION ACCESSORIES, HOSPITAL, AMBULANCE AND LABORATORY EQUIPMENT CONCEPTIONS

This certificate is valid for 3 years on condition that surveillance audits are carried out before the period of each year in accordance with the accreditation rules. With this certificate, the holder of the certificate has been audited on the address mentioned above by TRB Certification Body in accordance with the condition and requirements of the license contract and it has been registered that the company satisfies the conditions of the standard. This certificate is valid as long as the certificate holder follows TRB certification rules and the certificate is seen as valid on www.trb.com.de web site certificate inquiry section.

Certification Number : DE-QC-951
Date of Issue : 19.10.2018
Expiry Date : 18.10.2022
Certification Period : 3 Years (1. Year)
Printing Number : 03




General Manager



Deutsche
Akkreditierungsstelle
D-ZM-19486-01-00



CERTIFICATE

İNSPİTAL MEDİKAL TEKNOLOJİ ANONİM ŞİRKETİ

KARAOĞLAN MAHALLESİ KÜME EVLERİ NO: 745 GÖLBAŞI - ANKARA - TURKEY

DESIGN, DEVELOPMENT, PRODUCTION, INSTALLATION, DISTRIBUTION AND SERVICES OF MEDICAL GAS, MEDICAL AIR AND VACUUM SYSTEMS AND EQUIPMENTS, STAINLESS STEEL HOSPITAL EQUIPMENTS, SCRUB SINKS, ULTRASONIC CLEANING UNITS, ASPIRATION BAG SUCTION LINER AND ACCESSORIES, MEDICAL COPPER TUBINGS AND FITTINGS, ELECTROSURGICAL UNITS, SURGICAL SUCTION UNITS, OPERATING ROOM TABLES AND ACCESSORIES, OPERATING ROOM LAMPS, EXAMINATION LAMPS

with a scope of

EN ISO 13485:2016

Has established a management system in accordance
with international Medical Devices Quality Management System Standard

"Following elements of the standard are excluded"

"7.5.5" "7.5.7" "7.5.9.2"

Certificate No	: M 11038
Initial Certification Date	: 02 August 2018
Certification Date	: 28 July 2021
Expiration Date	: 27 July 2024

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cadde No. 15 Tepeören Tuzla
İstanbul / Turkey

Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

General Manager



Certificate is valid till expiration date,
subject to successful completion of
periodical surveillance audits.
Please contact above numbers for
detailed information.