EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Ackermann Instrumente GmbH
Eisenbahnstraße 65 - 67
78604 Rietheim-Weilheim
Germany

for the scope

Devices for Endoscopy, Scopes, Cannulas, Suction and Irrigation Systems, Shaver- Systems (see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-07-10
Valid until	2024-05-26
Registration no.	D1458100002
Report no.	P20-00999-178914
Stuttgart	2020-07-10

Head of Certification Body

Digitally signed by Bunic Gheorghe
Date: 2022.08.05 09:28:26 EEST
Reason: MoldSign Signature
Location: Moldova

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

ZLG-BS-248.10.06

For electronic publication only

Certificate

mdc medical device certification GmbH
certifies that

Ackermann Instrumente GmbH
Eisenbahnstraße 65 - 67
78604 Rietheim-Weilheim
Germany

for the scope

Design, manufacturing and distribution of active and non-active surgical instruments, surgical and endoscopic units, endoscopes and implants

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2020-02-10
Valid until	2023-02-09
Registration no.	D1458100001
Report no.	P19-01161-170154
Stuttgart	2020-02-10

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

ATTESTATION / *CERTIFICATE* **N° 7664 rev. 17**
Délivrée à Paris le 19 février 2021
Issued in Paris on February 19th, 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*

SOPRO
ZAC Athélia IV, Avenue des Genévriers
13705 LA CIOTAT CEDEX FRANCE

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

Dispositifs de gestion de gaz ou liquides en endoscopie et coelioscopie
Caméras dentaires
Système numérique de radiologie

Gas or liquid management devices for endoscopy and coelioscopy
Dental cameras
Radiological digital system

Voir document complémentaire GMED / See GMED additional document
n° 37749

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P181059, P601253, 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 P181059, P601253, 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 19th, 2021 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED SAS GROUPE LNE GMED SAS

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

GMED - 7664 rev. 17
Modifie le certificat 7664-16

GMED_b2p3_new2020-V0-04-

Ce document complémentaire GMED n° 37749 rev. 3 atteste de la validité du certificat CE n° 7664 rev. 17 au regard des informations listées ci-dessous.

This GMED additional document n° 37749 rev. 3 attests to the validity of CE certificate n° 7664 rev. 17 with regard to the information listed below.

Fabricant / *Manufacturer:*

SOPRO A Company of ACTEON Group
ZAC Athélia IV, Avenue des Genévriers
13705 LA CIOTAT CEDEX FRANCE

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Système de radiologie numérique dentaire *Digital dent x-ray system*	**SOPIX2**	**IIa**
Système de radiologie numérique dentaire *Digital dent x-ray system*	**SOPIX**	**IIa**
Système de radiologie numérique dentaire *Digital dent x-ray system*	**SOPIX INSIDE**	**IIa**
Système de radiologie numérique dentaire *Digital dent x-ray system*	**SOPIX^2 INSIDE**	**IIa**
Insufflateur pour coelioscopie *Laparoscopic insufflator*	**SOPRO 640-20**	**IIa**
Insufflateur pour coelioscopie *Laparoscopic insufflator*	**SOPRO 640-30**	**IIa**
Insufflateur pour coelioscopie *Laparoscopic insufflator*	**SOPRO 640-45**	**IIa**
Insufflateur d'endoscopie *Insufflator for endoscopy*	**SYMBIOZFLOW S698**	**IIa**

GMED 0459

GMED - 37749 rev. 3
Annule et remplace le document n° 37449 rev. 2

GMED SAS GMED SAS

DocuSigned by:
Lionel DREUX
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Lionel DREUX
Certification Director

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Système de radiologie numérique dentaire *Digital dent x-ray system*	**Taille 0 PSPIX2**	**IIa**
Système de radiologie numérique dentaire *Digital dent x-ray system*	**Taille 1 PSPIX2**	**IIa**
Système de radiologie numérique dentaire *Digital dent x-ray system*	**Taille 2 PSPIX2**	**IIa**
Système de radiologie numérique dentaire *Digital dent x-ray system*	**Taille 3 PSPIX2**	**IIa**
Système de radiologie numérique dentaire *Digital dental X-ray system*	**Xgenus digital CM**	**IIa**

Site couvert et Activités / *Location and Activities*

SOPRO A Company of ACTEON Group
Avenue des Genévriers - ZAC Athélia IV - 13705 LA CIOTAT CEDEX - FRANCE

Conception, fabrication et contrôle final / *Design, manufacture and final control*

GMED 0459

GMED - 37749 rev. 3
Annule et remplace le document n° 37449 rev. 2

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

Modifications

Identification des modifications apportées au certificat CE n° 7664 rev. 17 :
Identification of the modifications made to the CE certificate n° 7664 rev. 17:

Modification	Dossier / *File N°*	Date
Mise à jour du nom du fabricant *Update of the name of the manufacturer*	**P602952**	**09/03/2022** *03/09/2022*

GMED | **0459**

GMED - 37749 rev. 3
Annule et remplace le document n° 37449 rev. 2

DocuSigned by:
Lionel DREUX
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Lionel DREUX
Certification Director

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 7665 rev. 9

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

SOPRO A Company of ACTEON Group
ZAC Athélia IV, Avenue des Genévriers
13705 LA CIOTAT CEDEX FRANCE

pour les activités

for the activities

Conception, production, distribution et maintenance de caméras, de système numérique de radiologie, de lecteur digital de plaques, de plaques d'imagerie, de vidéolaparoscopes, de sources de lumières froides, de dispositifs de gestion de gaz ou liquides en endoscopie, coelioscopie et pour colonoscopie virtuelle

Design, manufacturing, distribution and service of cameras, digital X-ray system, digital imaging plate scanner, imaging plates, videolaparoscopes, cold light sources, gas or liquid management devices for endoscopy, coelioscopy and virtual colonoscopy

réalisées sur le(s) site(s) de

performed on the location(s) of

SOPRO A Company of ACTEON Group
ZAC Athélia IV - Avenue des Genévriers - 13705 LA CIOTAT CEDEX - FRA

est conforme aux exigences des normes internationales

complies with the requirements of the international standards

ISO 13485 : 2016

Début de validité */ Effective date :* **December 17th, 2021 (included)**
Valable jusqu'au */ Expiry date :* **December 23rd, 2024 (included)**
Etabli le */ Issued on :* **March 9th, 2022**

GMED SAS GMED SAS
GMED GROUPE LNE
DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT

Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 7665–9
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Annule et remplace le certificat 7665-8

GMED_SQ-F-V0-07-2018

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10401-2017-CE-CZS-NA-PS Rev. 6.0	PRJC-189266-2009-PRC-CZE	27 May 2024

This is to certify that the quality system of:

GCE, s.r.o.

Žižkova 381,583 01 Chotěboř, Czech Republic

For design, production and final product inspection/testing of:
MEDICAL DEVICES FOR USE WITH MEDICAL GASES

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik,15 March 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Sholeh Gheissar

Sholeh Gheissar
Principal assessor

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	**Description**	**Issue Date**
0.0	Supersedes DNV GL (NB0434) certificate No. 73547-2010-CE-CZS-NA 7.0 following transfer of notified body function to DNV Nemko Presafe AS (NB2460)	2017-11-01
1.0	Correction pagination	2018-07-11
2.0	Scope extension – added new variants of Pressure regulators integrated with cylinder valves - MediVital A and MediVital E	2018-08-22
3.0	Re-certification	2020-03-30
4.0	Scope Extension – added new models in Bold High Pressure Regulators, model MEDITEC Flow-metering devices, model MediFlowTec As listed in the List of Models dated 11-09-2020	2020-09-11
5.0	Removing models – Gas Switch, Gas Alarm C44, Gas Alarm G4, Gas Alarm MC7701, Gas Alarm Touch, as per List of Models dated 14-09-2020	2020-09-15
6.0	**Scope Extension – added new site (in bold)**	2021-03-15

Products covered by this Certificate:

Product Description	**Product Name**	**Class**
Medical devices for use with Medical Gases	Flow-metering devices (Ball flow meters, Flow selectors) Humidifiers Low pressure hoses Low pressure regulators Terminal Unit (for Anesthetic Gas Scavenging System) Suction equipment (Suction ejectors, Vacuum regulators) Demand Valve Gas Saver	IIa
Medical devices for use with Medical Gases	Pressure regulators integrated with cylinder valves Cylinder valves High Pressure Regulators Terminal Unit Ambulance Panel Central gas supply system Resuscitator Adjustable regulators	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	**Address**
GCE, s.r.o.	Žižkova 381, 583 01 Chotěboř, Czech Republic
ESAB Welding Products (Jiangsu)Co., Ltd.	**No.7, Xinjing West Road Zhangjiagang Economic and Technological Development Zone, Jiangsu, China 215600**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
262513-2018-AQ-CZS-NA-PS

Initial certification date:
11 May 2018

Valid:
02 July 2021 – 11 May 2024

This is to certify that the management system of

GCE Group AB

Murmansgatan 126, 212 25, Malmö, Sweden

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design, production, sales, distribution and service of medical gas equipment and devices for usage of medical gases.

Place and date:
Høvik, 14 January 2022

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Certificate no.: 262513-2018-AQ-CZS-NA-PS
Place and date: Høvik, 14 January 2022

Appendix to Certificate

GCE Group AB

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
GCE Group AB	Murmansgatan 126, 212 25, Malmö, Sweden	Management
GCE, s.r.o.	Žižkova 381, 583 01 Chotěboř, Czech Republic	Design, production, sales, distribution and service of medical gas equipment and devices for usage of medical gases.
GCE Norden AB	Murmansgatan 126, 212 25, Malmö, Sweden	Sales, service and customization of medical gas equipment and devices for usage of medical gases.
GCE GmbH	Weyherser Weg 8, 36043 Fulda, Germany	Sales medical gas equipment and devices for usage of medical gases. Service of concentrators.
GCE SAS	70, Rue du Puits Charles, 58403, LA CHARITE SUR LOIRE, France	Sales of medical gas equipment and devices for usage of medical gases. Service of concentrators.
ESAB Welding Products (Jiangsu) Co., Ltd.	No.7, xin jing West Road, Zhangjiagang Economic and Technological Development Zone Jiangsu Province China 215600	Production, sales, distribution and service of medical gas equipment and devices for usage of medical gases.
Gas Control Equipment Ltd.	100 Empress Park, Penny Lane, Haydock,Haydock, St Helens, WA11 9DB, United Kingdom	Design and sales of medical gas equipment and devices for usage of medical gases. Management of service of concentrators.
Gas Arc Group Ltd.	Vinces Road, Diss, Norfolk, IP22 4WW, United Kingdom	Design, production and sales of medical gas equipment and devices for usage of medical gases.

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Maxer Endoscopy GmbH
Eisenbahnstraße 102
78573 Wurmlingen
Germany

for the scope

surgical and endoscopic instruments as well as surgical equipment, medical fluid pump set, shafts urology -lithotripsy, nephroscopy, hysteroscopy (see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-11-03
Valid until	2024-05-26
Registration no.	D1192000020
Report no.	P20-01553-185987
Stuttgart	2020-11-03

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Certificate

mdc medical device certification GmbH
certifies that

Maxer Endoscopy GmbH
Eisenbahnstraße 102
78573 Wurmlingen
Germany

for the scope

development, production and distribution of surgical and endoscopic instruments and equipments

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2020-01-15
Valid until	2023-01-14
Registration no.	D1192000018
Report no.	P19-01109-153263
Stuttgart	2020-01-15

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

EC Certificate

TUVRheinland

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1015743-1

Manufacturer: W.O.M. World of Medicine GmbH
Salzufer 8
10587 Berlin
Germany

Products:
- Insufflators for Laparoscopy
- Irrigation Pumps for Arthroscopy
- Suction and Irrigation Pumps for Laparoscopy
- Irrigation Pumps/Scale for Hysteroscopy
- Multiindication Pumps
- Tube Sets for Insufflators, single-use
- Tube Sets for Insufflators, reusable
- Heating Tube Sets for Insufflators, reusable
- Inflow Tube Sets for Pumps, single-use
- Tube Sets for Pumps, reusable

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:
- Outflow Tube Sets for Pumps, single-use

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3321949- 770

Effective date: 2021-05-20

Expiry date: 2024-05-26

Issue date: 2021-05-20

TÜV Rheinland LGA Products GmbH
TÜVRheinland

TOV Rheinland LGA Pro mbH
Tillystra13,e 2 · 90431 NOrnberg · Germany

TOV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVR heinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1015743-1

Manufacturer: W.O.M. World of Medicine GmbH
Salzufer 8
10587 Berlin
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Activities
/01	W.O.M. World of Medicine GmbH Salzufer 8 10587 Berlin Germany	Manufacturing site
102	W.O.M. World of Medicine GmbH Alte Poststr. 11 96337 Ludwigsstadt Germany	Manufacturing site
103	W. 0. M. World of Medicine GmbH Kornergasse 21 96358 Reichenbach Germany	Manufacturing site

Report No.: 3321949- 770

Effective date: 2021-05-20

Expiry date: 2024-05-26

Issue date: 2021-05-20

TÜV Rheinland LGA Products GmbH
TÜVRheinland

TOV Rheinland LGA Products GmbH
Tillystra e 2 · 90431 Nurnberg · Germany

TOV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 1400667**

Certificate Holder: **W.O.M. World of Medicine GmbH**
Salzufer 8
10587 Berlin
Germany

including the locations according to annex

Scope: Development, manufacture, sales and service of products and accessories for minimally invasive surgery (MIS), electronic assemblies, and CNC machined components for the medical industry

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

Validity: The certificate is valid from 2020-07-18 until 2023-07-17.
First certification 2014

2021-02-10

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 32003001

Sometech Inc.

1201, 1204, Ace High-end Tower II, 61 Digital-ro 26-gil, Guro-gu, Seoul, Republic of KOREA

EN ISO 13485:2016

Design, Manufacture and Servicing of Medical Camera Systems, 3D Laparoscopy System (Endoscope), High Frequency Electrosurgical Device, Including Monopolar and Bipolar Type Electrodes, Radio Frequency Diathermy Device and Electrodes

Approves that the Medical Devices Quality Management System implemented for above scope.

Issue Date	30.01.2020
Expiry Date	29.01.2023

TÜRKAK BDS NO
YS-1E8B-B472

TÜRKAK
Tıbbi Cihazlar K. Y. S.
TS EN ISO/IEC 17021
AB-0044-YS

Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://tdbs.turkak.org.tr.

EC Declaration of Conformity

No. of certificate	**: No 20131114-DCSP001**
Manufacturer's Name	**: SOMETECH INC.**
Manufacturer's Address	**: (Ace High-end Tower II, Guro-dong) 1201ho, 61, Digital-ro 26gil, Seoul Korea**
declares, that the product	
Product Name	**: Medical camera system**
Model Name	**:VES-100 (LED)**
Classification	**Class I (according to the Rule 9 of Classification Criteria, annex Ⅸ, MDD 93/42/EEC)**
Applicable Harmonized Standard	**- EN 60601-1 [1990] Medical electrical equipment Part1: General requirements** **- EN 60601-1-2 [2001] Medical electrical equipment Part1: General requirements Section1.2 Collateral standard: Electromagnetic compatibility**

The product herewith complies with the requirements of the MD Directive 93/42/EEC and carries the "CE" mark accordingly.

CE

Seoul, Korea Nov 14, 2018

Sometech Inc.

Hee-Bong Yang / President

(President, on behalf of Sometech Inc.)