

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.

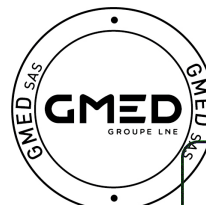
GMED certifies that, on the basis of the results contained in the file referenced P181059, P601253, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

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)



DocuSigned by:

Lionel DREUX

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Lionel DREUX

Certification Director

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)

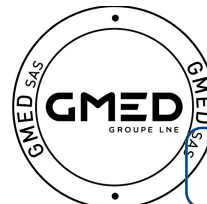
Etabli le / Issued on : March 9th, 2022



GMED 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



DocuSigned by:

Lionel DREUX

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Lionel DREUX
Certification Director

VIDEO CAMERAS

Full HD camera

SYMBIOZ *Cam*
Full HD



Reference	Designation
S_398_9000	SYMBIOZ CAM FULL HD CCU - EU
S_398_9001	SYMBIOZ CAM FULL HD CCU - US



Reference	Designation / Description
S_398_9002	SYMBIOZ CAM FULL HD CCU R - EU SYMBIOZ Cam Full HD Camera control unit with integrated recorder - EU
S_398_9003	SYMBIOZ CAM FULL HD CCU R - US SYMBIOZ Cam Full HD Camera control unit with integrated recorder - US



Reference	Designation / Description
S_398_8000	SYMBIOZ CAM SENSOR SYMBIOZ Cam Full HD - Camera head with integrated HD 15-35mm zoom coupler

SPECIFICATION OF THE CAMERA CONTROL UNIT (CCU)

S_398_9000 & S_398_9001 / S_398_9002 & S_398_9003

- Digital zoom up to 2.5x
- Application and user menus
- 6 optimized preset applications
- All functions available from the camera head
- Instant and contactless access to preset applications and personal profiles with the SCards*
- Unlimited number of profiles with personal presets up to 5
- Communication between SYMBIOZ Led & SYMBIOZ Flow thanks to ISYME concept
- Automatic compensation function for defective pixels
- Automatic white balance
- Freeze, mirror and gain functions
- Brightness, details, red and blue gains, gamma, color adjustments
- Noise reducer: OFF/ LOW / HIGH
- Electronic anti-moiré filter for flexible endoscopes
- On screen displayed adjustments
- Reset to the factory settings
- RF transmitter:
 - Type: RFID
 - Frequency: 13,56 MHz
 - Modulation feature: OOK
 - Transmitter power: 70 mW (+18 dBm)
- Video outputs:
 - CVBS: 1.0 V [P-P] / 75 ohms, Negative Sync
 - Y/C: Y: 1.0 V [P-P] / 75 ohms, C: 0.286 V [P-P] (NTSC), C: 0.3 V [P-P] V [P-P] (PAL) / 75 ohms, Negative Sync
 - RGB: 3 x 0.7 V [P-P] & 0.3V [P-P] / 75 ohms
 - HD-SDI: 0.8 V [P-P] / 75 ohms SMPTE292M
 - DVI-D: 3 x 0.7 Vcc & 0.3 Vcc / 75 ohms
- 2 peripheral outputs
- 7" 16/9 touch screen with intuitive interface
- Dimensions (W x H x D): 310 x 136 x 385mm
- Weight: 4300 g
- Protection type: IPX0 (not drip-proof)
- Power supply: 100 - 230 VAC / 50 - 60Hz
- Power consumption: 38 - 50 VA
- Two T2,5AL - 250 V fuses (Marked UL/CSA only)
- 18 languages
- Continuous service

Option S_398_9002 & S_398_9003

- Full HD Images and Videos recorder integrated (USB)

SPECIFICATION OF THE CAMERA HEAD

S_398_8000

- 3CMOS technology 1/3" Full HD sensors
- HD 15-35mm integrated zoom coupler
- 3 fully programmable buttons
- Free scope rotation and locking system
- Automatic or adjustable electronic shutter (1/50 to 1/1000000)
- Resolution: HDTV 1080p format: 1920 x 1080 pixels
- Definition: 1080 lines
- Active pixels area: 1920 x 1080 pixels
- Progressive Scan Technology
- Acquisition in native 16:9 format
- Sensitivity: 5 lux
- Signal / Noise ratio: 54 dB
- Cable length: 3 meters
- Dimensions (D x H): 149 x 53mm
- Weight: 270 g
- Protection type: IPX7 (waterproof)

Medical devices of class I - CE / Manufacturer: SOPRO™ (France) / Distributed by SOPRO, under the commercial brand COMEG

* For SCARD, see Accessories chapter