

EU DECLARATION OF CONFORMITY

(Annex IV of regulation 2017/745)



I undersigned Mr Denis PAPIN, General Manager of SURGIRIS SAS whose headquarters are located at 80 rue de la Gare 59170 CROIX France, registered on manufacturer number : **FR-MF-00004556**, certify and declare on my sole responsibility that the medical devices following (basic UDI-DI : 37015026000138).

SURGICAL AND EXAMINATION LIGHT				
Model	Type	Reference	Designation	UDI-DI
EPURE	EPURE	CEPURE-01	EPURE DOUBLE YOKE	3701502627210
	EPUREF	CEPURE-02	EPURE SINGLE YOKE	3701502627203
	EPUREST	CEPURE-05	EPURE ST DOUBLE YOKE	3701502627173
	EPURESTF	CEPURE-06	EPURE ST SINGLE YOKE	3701502627166
	EPURE4	CEPURE-03	EPURE 4 SINGLE YOKE	3701502627197
	EPURE4M	CEPURE-04	EPURE 4 SINGLE YOKE FOR SWING	3701502636090
	EPURE4ST	CEPURE-07	EPURE 4ST SINGLE YOKE	3701502636106
	EPURE4STM	CEPURE-08	EPURE 4ST SINGLE YOKE FOR SWING	3701502636083
X3MT	X3C	CX3C	X3MT DOUBLE YOKE	3701502626503
	X3CF	CX3CF	X3MT SINGLE YOKE	3701502626497
X2MT	X2C	CX2C	X2MT DOUBLE YOKE	3701502626602
	X2CF	CX2CF	X2MT SINGLE YOKE	3701502626596
DIASYS	DIASYS	CDIASYS-01	NEW DIASYS	3701502627753
	DIASYS+	CDIASYS-02	NEW DIASYS +	3701502627746
ACCESSORIES				
Model	Type	Reference	Designation	UDI-DI
ALIM-XMT	ALIM-XMT	ALIM-XMT	LIGHTING POWER SUPPLY UNIT FOR XMT SERIES INSTALLATION ON THE FLANGE	3701502631453
ALIM-EPURE	ALIM-EPURE	ALIM-EPURE	LIGHTING POWER SUPPLY UNIT EPURE INSTALLATION ON THE FLANGE	3701502632559
ALIM-EPURE4	ALIM-EPURE4	ALIM-EPURE4	LIGHTING POWER SUPPLY UNIT EPURE4 INSTALLATION ON THE FLANGE	3701502636724
ALIM-DIASYS	ALIM-DIASYS	ALIM-DIASYS	LIGHTING POWER SUPPLY UNIT DIASYS INSTALLATION ON THE FLANGE	3701502632641
EMERGEILED	EMERGEILED 1 EPURE 1.5H	EMERGEILED-1E-1.5H	EMERGENCY SUPPLY UNIT FOR 1 CUPOLA TYPE EPURE - BACKUP 1.5H FOR EPURE OR 4H FOR EPURE4	3701502624943
	EMERGEILED 1 EPURE 3H	EMERGEILED-1E-3H	EMERGENCY SUPPLY UNIT FOR 1 CUPOLA TYPE EPURE - BACKUP 3H FOR EPURE OR 8H FOR EPURE4	3701502624936
	EMERGEILED 2 EPURE 1.5H	EMERGEILED-2E-1.5H	EMERGENCY SUPPLY UNIT FOR 2 CUPOLA TYPE EPURE - BACKUP 1.5H FOR EPURE OR 4H FOR EPURE4	3701502624721
	EMERGEILED 2 EPURE 3H	EMERGEILED-2E-3H	EMERGENCY SUPPLY UNIT FOR 2 CUPOLA TYPE EPURE - BACKUP 3H FOR EPURE OR 8H FOR EPURE4	3701502624707
	EMERGEILED 1 SURGILED 1H	EMERGEILED-1S-1H	EMERGENCY SUPPLY UNIT 1 HOUR FOR 1 CUPOLA TYPE SURGILED [XMT,KALEA]	3701502624875
	EMERGEILED 1 SURGILED 2H	EMERGEILED-1S-2H	EMERGENCY SUPPLY UNIT 2 HOURS FOR 1 CUPOLA TYPE SURGILED [XMT,KALEA]	3701502624868
	EMERGEILED 1 SURGILED 4H	EMERGEILED-1S-4H	EMERGENCY SUPPLY UNIT 4 HOURS FOR 1 CUPOLA TYPE SURGILED [XMT,KALEA]	3701502624844
	EMERGEILED 2 SURGILED 1H	EMERGEILED-2S-1H	EMERGENCY SUPPLY UNIT 1 HOUR FOR 2 CUPOLA SURGILED [XMT,KALEA]	3701502624660
	EMERGEILED 2 SURGILED 2H	EMERGEILED-2S-2H	EMERGENCY SUPPLY UNIT 2 HOURS FOR 2 CUPOLA TYPE SURGILED [XMT,KALEA]	3701502624653
	EMERGEILED RENOV	EMERGEILED RC 1 LIGHT 1.5H	EMERGEILEDRC-1E-S1	RENOVATION EMERGENCY SUPPLY UNIT 1.5 HOUR FOR 1 EPURE OR 4H FPR EPURE4 + WALL CONTROL UNIT
EMERGEILED RC 1 LIGHT 3H		EMERGEILEDRC-1E-S2	RENOVATION EMERGENCY SUPPLY UNIT 3 HOUR FOR 1 EPURE OR 8HOUR FOR 1 EPURE 4 + WALL CONTROL UNIT	3701502624462
EMERGEILED RC 2 LIGHT 1.5H		EMERGEILEDRC-2E-S1	RENOVATION EMERGENCY SUPPLY UNIT FOR 2 CUPOLA 1.5H FOR EPURE OR 4H FOR EPURE4 + WALL CONTROL UNIT	3701502624370
EMERGEILED RC 2 LIGHT 3H		EMERGEILEDRC-2E-S2	RENOVATION EMERGENCY SUPPLY UNIT FOR 2 CUPOLA 3H FOR EPURE OR 8H FOR EPURE4 + WALL CONTROL UNIT	3701502624363
EMERGEILED RC 1 LIGHT 1H		EMERGEILEDRC-1S-S1	RENOVATION EMERGENCY SUPPLY UNIT 1 HOUR FOR 1 CUPOLA TYPE SURGILED [XMT, KALEA] + WALL CONTROL UNIT	3701502624431
EMERGEILED RC 1 LIGHT 2H		EMERGEILEDRC-1S-S2	RENOVATION EMERGENCY SUPPLY UNIT 2 HOUR FOR 1 CUPOLA TYPE SURGILED [XMT, KALEA] + WALL CONTROL UNIT	3701502624424
EMERGEILED RC 2 LIGHT 1H		EMERGEILEDRC-2S-S1	RENOVATION EMERGENCY SUPPLY UNIT 1 HOUR FOR 2 CUPOLA TYPE SURGILED [XMT, KALEA] + WALL CONTROL UNIT	3701502624332
EMERGEILED RC 2 LIGHT 2H		EMERGEILEDRC-2S-S2	RENOVATION EMERGENCY SUPPLY UNIT 1 HOUR FOR 2 CUPOLA TYPE SURGILED [XMT, KALEA] + WALL CONTROL UNIT	3701502624325

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SURGIRIS
SMART VISION

DEPORTED POWER SUPPLY	ALIM-DEP-01-006	ALIM-DEP-01-006	DEPORTED POWER SUPPLY FOR 1 LIGHT TYPE EPURE OR EPURE4	3701502632825
	ALIM-DEP-01-008	ALIM-DEP-01-008	DEPORTED POWER SUPPLY FOR 1 X1, XMT	3701502632801
	ALIM-DEP-02-004	ALIM-DEP-02-004	DEPORTED POWER SUPPLY FOR 2 LIGHT TYPE EPURE OR EPURE4	3701502632764
	ALIM-DEP-02-006	ALIM-DEP-02-006	DEPORTED POWER SUPPLY FOR 2 LIGHT TYPE SURGILED [X1,XMT]	3701502632740
	ALIM-DEP-05-001	ALIM-DEP-05-001	DEPORTED POWER SUPPLY FOR 1 LIGHT TYPE EPURE OR EPURE4 - FOR TECHNICAL LOCAL AERA	3701502632702
	ALIM-DEP-05-003	ALIM-DEP-05-003	DEPORTED POWER SUPPLY FOR 1 X1, XMT - FOR TECHNICAL LOCAL AERA	3701502632689
	ALIM-DEP-06-001	ALIM-DEP-06-001	DEPORTED POWER SUPPLY FOR 2 LIGHT TYPE EPURE OR EPURE4 - FOR TECHNICAL LOCAL AERA	3701502632672
	ALIM-DEP-06-003	ALIM-DEP-06-003	DEPORTED POWER SUPPLY FOR 2 LIGHT TYPE SURGILED [X1,XMT] - FOR TECHNICAL LOCAL AERA	3701502632658
	ALIM-DIASYS-S1	ALIM-DIASYS-S1	LIGHTING POWER SUPPLY UNIT DIASYS - IN BOX WITH BACKUP	3701502632610
RM-CAM-E-01	RM-CAM-E-01	RM-CAM-E-01	CAMERA CONTROL UNIT BUILT-IN / 24 VDC	3701502616443
RM-CAM-E-02	RM-CAM-E-02	RM-CAM-E-02	CAMERA CONTROL UNIT BUILT-IN / 100-240 VAC	3701502616436
RM-CAM-S-03	RM-CAM-S-03	RM-CAM-S-03	CAMERA CONTROL UNIT WALL / 24 VDC	3701502616269
RM-CAM-S-04	RM-CAM-S-04	RM-CAM-S-04	CAMERA CONTROL UNIT WALL / 100-240 VAC	3701502616252
RM-ECL-E-01	RM-ECL-E-01	RM-ECL-E-01	LIGHT CONTROL UNIT BUILT-IN / 24 VDC	3701502616245
RM-ECL-E-02	RM-ECL-E-02	RM-ECL-E-02	LIGHT CONTROL UNIT BUILT-IN / 100-240 VAC	3701502616238
RM-ECL-S-03	RM-ECL-S-03	RM-ECL-S-03	LIGHT CONTROL UNIT WALL / 24DC	3701502616061
RM-ECL-S-04	RM-ECL-S-04	RM-ECL-S-04	LIGHT CONTROL UNIT WALL / 100-240VAC	3701502616054
HANDLE	POIGNEE STERILISABLE	POIG0003	GREY HANDLE STERELISABLE FOR LED SURGICAL LIGHT	3701502636502
		POIG0012	STERILIZABLE HANDLE FOR HD CAMERA V2 BLACK SEAL	3701502616993
		POIG0016	GREY HANDLE STERELISABLE FOR 4K CAMERA	3760194370743
WIRELESS CAMERA	CAMERA-WIRELESS	CAMERA-WIRELESS	NOMADEO VIDEO CAMERA HD WITH VIDEO RECEIVER	3701502636182
		CAMERA-WIRELESS-02	HDMI NOMADEO VIDEO CAMERA HD WITH VIDEO RECEIVER	3701502636199
	CAMHD-WL-001	VID-CAM-HD-WL-0001	NOMADEO SMART VIDEO CAMERA HD WITH VIDEO RECEIVER AND REMOTE CONTROL NF PLUG	3701502636205
		VID-CAM-HD-WL-0002	NOMADEO SMART VIDEO CAMERA HD WITH VIDEO RECEIVER AND REMOTE CONTROL UK PLUG	3701502636212
		VID-CAM-HD-WL-0003	NOMADEO SMART VIDEO CAMERA HD WITH VIDEO RECEIVER AND REMOTE CONTROL US PLUG	3701502636229
		VID-CAM-HD-WL-0004	NOMADEO SMART VIDEO CAMERA HD WITH VIDEO RECEIVER AND REMOTE CONTROL SW PLUG	3701502636236
		VID-CAM-4K-WL-0001	NOMADEO VIDEO CAMERA 4K WITH HDMI VIDEO RECEIVER	3760194370262
CAM4K-WL-001				



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These medical devices are in conformity and comply to the essential requirements of the regulation (EU) 2017/745, as well as the main technical standards concerning surgical lightings (NF EN 60601-1, NF EN 60601-1-2, CEI 60601-2-41, ETSI 300328 and IEC 60529). They also comply with any other current technical and safety standards.

On the other hand, these medical devices are in conformity with the directive 2011/65/UE on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and these successive adaptations.

These medical devices are class I medical devices as defined by Annex VIII of the Regulation (EU) 2017/745.

I undertake to enforce all the related regulatory and standards developments that have to be applied on these devices.

DONE AT CROIX, ON THE 21/11/2024

DENIS PAPIN

GENERAL MANAGER



SURGIRIS
80, rue de la Gare
59170 CROIX
Tel. 03 20 16 07 93
Fax 03 20 95 40 19
SIRET 437 760 812 00044
VAT - FR 30 437 760 812

