

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-000004556**, 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
	X3CV	CX3CV	X3MT DOUBLE YOKE + PREPA VIDEO	3701502626473
	X3CF	CX3CF	X3MT SINGLE YOKE	3701502626497
	X3CFV	CX3CFV	X3MT SINGLE YOKE + PREPA VIDEO	3701502626480
X2MT	X2C	CX2C	X2MT DOUBLE YOKE	3701502626602
	X2CV	CX2CV	X2MT DOUBLE YOKE + PREPA VIDEO	3701502626572
	X2CF	CX2CF	X2MT SINGLE YOKE	3701502626596
	X2CFV	CX2CFV	X2MT SINGLE YOKE + PREPA VIDEO	3701502626589
KALEA 30	K30	CK30	KALEA 30 DOUBLE YOKE	3701502627098
	K30V	CK30V	KALEA 30 DOUBLE YOKE + PREP VIDEO	3701502627067
	K30F	CK30F	KALEA 30 SINGLE YOKE	3701502627081
	K30FV	CK30FV	KALEA 30 SINGLE YOKE + PREP VIDEO	3701502627074
KALEA 20	K20	CK20	KALEA 20 DOUBLE YOKE	3701502627135
	K20V	CK20V	KALEA 20 DOUBLE YOKE + PREP VIDEO	3701502627104
	K20F	CK20F	KALEA 20 SINGLE YOKE	3701502627128
	K20FV	CK20FV	KALEA 20 SINGLE YOKE + PREP VIDEO	3701502627111
X1	X1	CX1	X1 SINGLE YOKE	3701502626657
	X1F	CX1F	X1 FRONTAL YOKE	3701502626640
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-KALEA	ALIM-KALEA	ALIM-KALEA	LIGHTING POWER SUPPLY UNIT FOR KALEA SERIES INSTALLATION ON THE FLANGE	3701502632528
ALIM-DIASYS	ALIM-DIASYS	ALIM-DIASYS	LIGHTING POWER SUPPLY UNIT DIASYS INSTALLATION ON THE FLANGE	3701502632641
ALIM-X1	ALIM-X1	ALIM-X1	LIGHTING POWER SUPPLY UNIT X1 INSTALLATION ON THE FLANGE	3701502631538
EMERGILED	EMERGILED 1 EPURE 1.5H	EMERGILED-1E-1.5H	EMERGENCY SUPPLY UNIT FOR 1 CUPOLA TYPE EPURE - BACKUP 1.5H FOR EPURE OR 4H FOR EPURE4	3701502624943
	EMERGILED 1 EPURE 3H	EMERGILED-1E-3H	EMERGENCY SUPPLY UNIT FOR 1 CUPOLA TYPE EPURE - BACKUP 3H FOR EPURE OR 8H FOR EPURE4	3701502624936
	EMERGILED 2 EPURE 1.5H	EMERGILED-2E-1.5H	EMERGENCY SUPPLY UNIT FOR 2 CUPOLA TYPE EPURE - BACKUP 1.5H FOR EPURE OR 4H FOR EPURE4	3701502624721
	EMERGILED 2 EPURE3H	EMERGILED-2E-3H	EMERGENCY SUPPLY UNIT FOR 2 CUPOLA TYPE EPURE - BACKUP 3H FOR EPURE OR 8H FOR EPURE4	3701502624707
	EMERGILED 1 SURGILED 1H	EMERGILED-1S-1H	EMERGENCY SUPPLY UNIT 1 HOUR FOR 1 CUPOLA TYPE SURGILED [XMT,KALEA]	3701502624875

EU DECLARATION OF CONFORMITY

(Annex IV of regulation 2017/745)

	EMERGILED 1 SURGILED 2H	EMERGILED-1S-2H	EMERGENCY SUPPLY UNIT 2 HOURS FOR 1 CUPOLA TYPE SURGILED [XMT,KALEA]	3701502624868
	EMERGILED 1 SURGILED 4H	EMERGILED-1S-4H	EMERGENCY SUPPLY UNIT 4 HOURS FOR 1 CUPOLA TYPE SURGILED [XMT,KALEA]	3701502624844
	EMERGILED 2 SURGILED 1H	EMERGILED-2S-1H	EMERGENCY SUPPLY UNIT 1 HOUR FOR 2 CUPOLA SURGILED [XMT,KALEA]	3701502624660
	EMERGILED 2 SURGILED 2H	EMERGILED-2S-2H	EMERGENCY SUPPLY UNIT 2 HOURS FOR 2 CUPOLA TYPE SURGILED [XMT,KALEA]	3701502624653
	EMERGILED 1 X1 1H	EMERGILED-1X-1H	EMERGENCY SUPPLY UNIT 2 HOURS FOR 1 CUPOLA TYPE X1	3701502624790
	EMERGILED 1 X1 2H	EMERGILED-1X-2H	EMERGENCY SUPPLY UNIT 2 HOURS FOR 1 CUPOLA TYPE X1	3701502624783
EMERGILED RENOV	EMERGILED RC 1 LIGHT 1.5H	EMERGILEDRC-1E-S1	RENOVATION EMERGENCY SUPPLY UNIT 1.5 HOUR FOR 1 EPURE OR 4H FPR EPURE4 + WALL CONTROL UNIT	3701502624479
	EMERGILED RC 1 LIGHT 3H	EMERGILEDRC-1E-S2	RENOVATION EMERGENCY SUPPLY UNIT 3 HOUR FOR 1 EPURE OR 8HOUR FOR 1 EPURE 4 + WALL CONTROL UNIT	3701502624462
	EMERGILED RC 2 LIGHT 1.5H	EMERGILEDRC-2E-S1	RENOVATION EMERGENCY SUPPLY UNIT FOR 2 CUPOLA 1.5H FOR EPURE OR 4H FOR EPURE4 + WALL CONTROL UNIT	3701502624370
	EMERGILED RC 2 LIGHT 3H	EMERGILEDRC-2E-S2	RENOVATION EMERGENCY SUPPLY UNIT FOR 2 CUPOLA 3H FOR EPURE OR 8H FOR EPURE4 + WALL CONTROL UNIT	3701502624363
	EMERGILED RC 1 LIGHT 1H	EMERGILEDRC-1S-S1	RENOVATION EMERGENCY SUPPLY UNIT 1 HOUR FOR 1 CUPOLA TYPE SURGILED [XMT, KALEA] + WALL CONTROL UNIT	3701502624431
	EMERGILED RC 1 LIGHT 2H	EMERGILEDRC-1S-S2	RENOVATION EMERGENCY SUPPLY UNIT 2 HOUR FOR 1 CUPOLA TYPE SURGILED [XMT, KALEA] + WALL CONTROL UNIT	3701502624424
	EMERGILED RC 2 LIGHT 1H	EMERGILEDRC-2S-S1	RENOVATION EMERGENCY SUPPLY UNIT 1 HOUR FOR 2 CUPOLA TYPE SURGILED [XMT, KALEA] + WALL CONTROL UNIT	3701502624332
	EMERGILED RC 2 LIGHT 2H	EMERGILEDRC-2S-S2	RENOVATION EMERGENCY SUPPLY UNIT 1 HOUR FOR 2 CUPOLA TYPE SURGILED [XMT, KALEA] + WALL CONTROL UNIT	3701502624325
ALIM DEPORTEE	ALIM-DEP-01-006	ALIM-DEP-01-006	DEPORTED POWER SUPPLY FOR 1 LIGHT TYPE EPURE OR EPURE4	3701502632825
	ALIM-DEP-01-007	ALIM-DEP-01-007	DEPORTED POWER SUPPLY FOR 1 KALEA	3701502632818
	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-02-005	ALIM-DEP-02-005	DEPORTED POWER SUPPLY FOR 2 LIGHT TYPE SURGILED [KALEA]	3701502632757
	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-05-002	ALIM-DEP-05-002	DEPORTED POWER SUPPLY FOR 1 KALEA - FOR TECHNICAL LOCAL AERA	3701502632696
	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-06-002	ALIM-DEP-06-002	DEPORTED POWER SUPPLY FOR 2 LIGHT TYPE SURGILED [KALEA] - FOR TECHNICAL LOCAL AERA	3701502632665
	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
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
POIGNEE	POIGNEE STERILISABLE	POIG0003	GREY HANDLE STERELISABLE FOR LED SURGICAL LIGHT	3701502636502
		POIG0012	STERILIZABLE HANDLE FOR HD CAMERA V2 BLACK SEAL	3701502616993
CAMERA-WIRELESS	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		

UE DECLARATION OF CONFORMITY

ANNEX IV OF REGULATION 2017/745

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

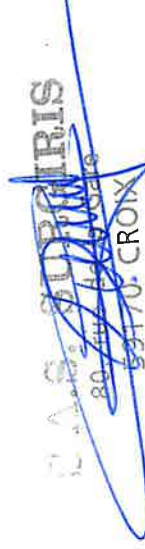
These medical devices are in conformity and comply to the essential requirements of the regulation (EU) 2017/745, as well as the main technical standards concerning surgical lightings (NF EN 60601-1, NF EN 60601-1-2, CEI 60601-2-41, ETSI 300328 and IEC 60529).
They also comply with any other current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

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

DONE AT CROIX, ON THE 18/07/2023

DENIS PAPIN
GENERAL MANAGER


S.A.S. SURGIRIS
80 Avenue de la République
93170. CROIX

Tél. 03 20 16 07 93
Fax 03 20 95 40 19
N° SIRET 437 760 812 00044
TVA N° FR 50 437 760 812

