EC COMPLIANCE DECLARATION

(Annex II of the Directive 93/42/EC)

SURGIRIS
SMART VISION

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 : 3701502600033C).

PHOTODYNAMIC THERAPY LAMP			
Model	**Type**	**Reference**	**Designation**
DERMARIS	DERMARIS	CDERMARIS-01	DERMARIS LIGHT
ACCESSORIES			
Model	**Type**	**Reference**	**Designation**
POIGNEE	POIGNEE STERILISABLE	POIG0003	GREY STERILIZABLE HANDLE FOR LED SURGICAL LIGHT

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These medical devices are class IIa medical devices as defined by Annex IX of the Directive 93/42/EEC and bear the CE1370 marking from Bureau Veritas Italia – Div. Certificazione – Viale Monza 347 - 20126 Milano, ITALY.

These medical devices are in conformity and comply to the essential requirements of the Directive 93/42/ECC (according to the appendix II), to the Directive 2007/47/EEC, as well as the main technical standards concerning PhotoDynamic Therapy Lamp (NF EN 60601-1, NF EN 60601-1-2, CEI 60601-2-57, 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

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