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 and their accessories (basic UDI-DI : 3701502600023A).

TRYPODE FIXE			
GMDN Code : 16793			
Model	**Type**	**Reference**	**Designation**
TRY1500-F	TRY1500,F,16FL-NF,24PC	TRY1500-F-01	TRY1500 F 16FL NF, 24 PC MOSAIC
	TRY1500,F,12FL-BS,24PC	TRY1500-F-02	TRY1500 F 12 FL BS PENLON, 24 PC MOSAIC
	TRY1500,F,16FL-DIN, 24PC	TRY1500-F-03	TRY1500 F 16 FL DIN GREG, 24 PC MOSAIC
	TRY1500,F,16FL-DIN,12PC	TRY1500-F-04	TRY1500 F 16 FL DIN GREG, 12 PC FELLER
TRY1100-F	TRY1100,F,8FL-NF,22PC	TRY1100-F-01	TRY1100 F8 FL NF, 22PC MOSAIC

TRYPODE MOBILE			
GMDN Code : 42060			
Model	**Type**	**Reference**	**Designation**
TRY1500-M	TRY1500,M,16FL-NF,24PC	TRY1500-M-01	TRY1500 M 16FL NF, 24 PC MOSAIC
	TRY1500,M,12FL-BS,24PC	TRY1500-M-02	TRY1500 M 12 FL BS PLN, 24 PC MOSAIC
	TRY1500,M,16FL-DIN,24PC	TRY1500-M-03	TRY1500 M 16FL DIN GREG, 24 PC MOSAIC
	TRY1500,M,16FL-DIN,12PC	TRY1500-M-04	TRY1500 M 16 FL DIN GREG, 12 PC FELLER
TRY1100-M	TRY1100,M,8FL-NF,22PC	TRY1100-M-01	TRY1100 M 8FL NF, 22PC MOSAIC

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ANNEX II OF THE DIRECTIVE 93/42/EC

These devices are class IIb medical devices as defined by the European Medical Device Directive 93/42/EEC according to the appendix IX and bear the CE1370 marking from Bureau Veritas Italia – Div. Certificazione - Via Miramare 15 - 20131 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 columns (IEC60601-1, ISO 7396-1, ISO5359 and ISO 11197). 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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Declaration valid until : 26/05/2024
Certificat CE lié : IT279419-2 Rev 29/04/21
REG-CER-TRYPODE-EN V010 18/07/2023

CE 1370 RoHS2 2011/65/EU