

## EC Declaration of Conformity

Manufacturer: **METRUM CRYOFLEX** Sp. z o. o., Sp. k.

Address: ul. Zielna 29, 05-082 Blizne Łaszczyńskiego, Poland

Phone.: +48 22 33 13 750, fax: +48 22 33 13 766

accepts full responsibility to declare that the medical devices of **class IIb** (rule 9) for cryosurgery with cryoprobes and ligators (Annex 1: List of application parts of Cryo-S Electric II device):

### CRYO-S Electric II

conform to the Essential Requirements of the Council Directive **93/42/EEC** and **2007/47/EC** and the Act of 20 May 2010 r. on medical devices **Dz.U. 2010 Nr 107 poz. 679**.

Listed medical devices fulfil bellow standards:

**EN 60601-1** Medical electrical equipment. General requirements for basic safety and essential performance.

**EN 60601-1-1-2** Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.

**EN 60601-1-6** Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability.

**EN 62366-1** Medical devices – Part 1: Application of usability engineering to medical devices

**EN 62304** Medical device software. Software life-cycle processes.

**EN ISO 10993-1** Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

**EN ISO 17664** Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices.

**EN 1041** Information supplied by the manufacturer of medical devices.

**EN ISO 15223-1** Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.

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**Zarząd / Headoffice**  
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05-092 Łomianki

**Produkcja / Manufacture**  
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**EN ISO 14971** Medical devices. Application of risk management to medical devices.

**Metrum CryoFlex** has established and maintains the Quality Management System certified to **EN ISO 13485** standard.

The conformity assessment was made according to the Annex II of the directive 93/42/EEC (excluding section 4.) under surveillance the Notified Body No. **2274**, **TUV NORD Polska Sp. z o.o.**, ul. Mickiewicza 29, 40-085 Katowice, phone: +48 32 786464, fax: +48 32 7864601.

Therefore, the above-mentioned medical devices can be marked with the following sign:



*Blizne Łaszczyńskiego, 23 September 2019*

President of the Board

  
Wiesław Brojek

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**Annex 1: List of application parts of Cryo-S Electric II device**
**Name and type of application part**

I. CRYO-S contact cryosurgical probes (detachable, reusable, for sterilization)

Types:

- |                    |                  |
|--------------------|------------------|
| 1. A-08/20/N/RF,   | 26. G-50/15/RF,  |
| 2. A-08/90/N/RF,   | 27. G-60/RF,     |
| 3. A-08/90/R/RF,   | 28. G-70/RF,     |
| 4. A-13/80/R/RF,   | 29. GH-1/RF,     |
| 5. A-13/80/T/RF,   | 30. L-10A/RF,    |
| 6. A-13/120/R/RF,  | 31. L-10P/RF,    |
| 7. A-13/120/T/RF,  | 32. L-25/RF,     |
| 8. A-16/80/RF,     | 33. L-30/RF,     |
| 9. A-25/170/R/RF,  | 34. L-40/RF,     |
| 10. A-25/220/R/RF, | 35. L-50/RF,     |
| 11. A-30/250/R/RF, | 36. L-60/RF,     |
| 12. A-30/300/R/RF, | 37. L-70/RF,     |
| 13. A-30/500/R/RF, | 38. OP-C013/RF,  |
| 14. D-10/RF,       | 39. OP-G014/RF,  |
| 15. D-21/RF,       | 40. OP-H015L/RF, |
| 16. D-22/RF,       | 41. OP-L008/RF,  |
| 17. D-23/RF,       | 42. OP-N008/RF,  |
| 18. D-30/RF,       | 43. OP-R009/RF,  |
| 19. G-10/20/RF,    | 44. OP-R010L/RF, |
| 20. G-10/22/RF,    | 45. OP-R010S/RF, |
| 21. G-10/24/RF,    | 46. OP-R011L/RF, |
| 22. G-20/RF,       | 47. OP-R102/RF,  |
| 23. G-30/2/RF,     | 48. OP-V008/RF,  |
| 24. G-30/RF,       | 49. P-10/RF.     |
| 25. G-30SIJ/RF     |                  |

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