



AGENȚIA MEDICAMENTULUI  
ȘI DISPOZITIVELOR MEDICALE

## REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire	DM000579791										
I.2. Declarația de conformitate CE	Declarație de conformitate CE	Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		DM000579791	ACCESORIU ELECTROCHIR		CABLU PENTRU ELECTROD NEUTRU REUTILIZABIL	F7923	Italia	FIAB SPA	LABROMED LABORATOR S.R.L.	Rg04-000190	14-08-2023	

[Создать фильтр](#)



## EU DECLARATION OF CONFORMITY according to Regulation (EU) 2017/745

### EN

Manufacturer: FIAB SpA  
Registered address: Via Costoli 4, 50039 Vicchio (FI), Italia  
Single Registration Number: IT-MF-000005988  
Basic UDI-DI: 80330032630600001P4  
Product name/ Intended Purpose: Cable connection between plates and electrosurgery  
Models: See list in Attachment  
Technical Documentation File: TDF 306  
Risk Class (MDR Annex VIII): I  
Conformity assessment procedure performed: Annex IV (EU Declaration of Conformity)

Technical standards and/or  
Common Specifications applied:

EN 60601-1 [2006/A1:2013] - EN 60601-1-2 [2015] - EN 60601-2-2 [2017] - EN ISO 10993-1[2020] - EN ISO 13485 [2016] - EN ISO 14971 [2019] - EN ISO 15223-1[2021] - EN ISO 20417 [2021]

With this Declaration of Conformity, issued under the sole responsibility of FIAB SpA as the Manufacturer, we hereby declare

- that the medical devices specified meet the provision of the Regulation (EU) 2017/745 for medical devices
- that the procedures of FIAB quality management system according to ISO 13485 have been followed, Certificate of Registration no.MD77846 issued by BSI
- that the products do not contain medicinal substances, elements of animal origin or their derivatives, human blood derivatives, and are latex free

Signature:

Vicchio, 14/12/2022

Alberto Calabrò  
Managing Director

Declaration Code EU-00000414-306 First issued: 25/05/2021  
Cod 99500038MD4B Last revised: 14/12/2022

Pagina 1 di 2





## EU DECLARATION OF CONFORMITY according to Regulation (EU) 2017/745

EN

### Attachment of EU Declaration of Conformity – List of models

F7902 - F7902-S - F7902/24 - F7902/3MT - F7902/4 - F7903 - F7903/F - F7904 - F7922 - F7922/24 -  
F7922/2MT - F7922/4 - F7922/WB - F7923 - F7923/F - F7924

Declaration Code	EU-00000414-306	First issued:	25/05/2021
Cod	99500038MD4B	Last revised:	14/12/2022

Pagina 2 di 2

