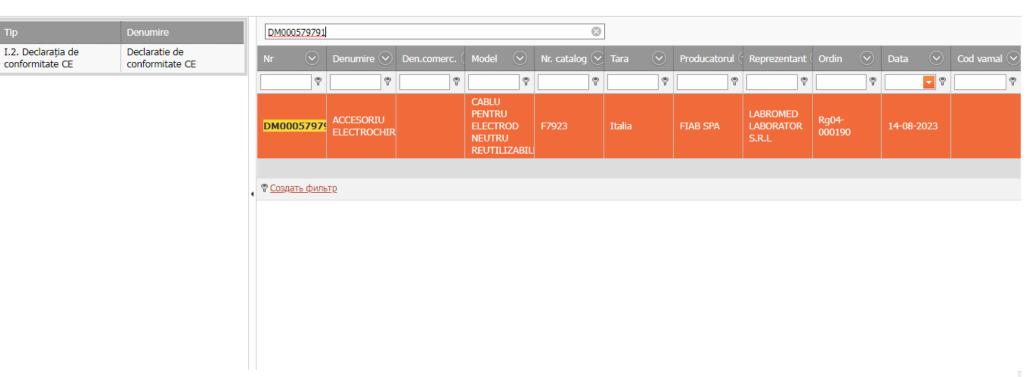


REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE





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:	803300326306000001P4
Product name/ Intended Purpose Models:	Cable connection between plates and electrosurgery 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 herby 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,

Vicchio, 14/12/2022

Alberto Calabrò Managing Director

EU-00000414-306

First issued: Last revised: 25/05/2021 14/12/2022

Cod 99500038MD4B

Declaration Code

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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:

Last revised:

25/05/2021 14/12/2022

Cod 99500038MD4B

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