

DECLARACIÓN DE CONFORMIDAD UE EU DECLARATION OF CONFORMITY

FABRICANTE: AB MEDICA GROUP S.A
MANUFACTURER:

DIRECCIÓN: Sede Social / Headquarter: c/ Jericó, 10 Bis Interior. 08035 Barcelona. (ESP)
España.

ADDRESS Oficinas y Almacén / Office and Warehouse : Avda. Salvatella, 4. P.I Salvatella
(ESP) España 08210 Barberà del Vallès. Barcelona (ESP)
Fábrica / Factory: C/ Llobateras 14-18, Talleres 7. N.4.6. P.I Santiga (ESP)
España 08210 Barberà del Vallès. (ESP)

EUDAMED SRN: ES-MF-000000582

Declara bajo su exclusiva responsabilidad que los productos fabricados:
Declare under their responsibility that the manufactured products:

| | | | |
|--|--|--------------------------|-------------------------------|
| Nombre <i>Name</i> | Papeles de registro médico <i>Recording charts for medical equipment</i> | REF <i>REF</i> | Ver Anexo <i>See Annex</i> |
| Marca <i>Trademark</i> | LESSA <i>LESSA</i> | | |
| UDI-DI Básico <i>Basic UDI-DI</i> | 84287631029PAPNOGRIDB4 | | |
| Código CND/ GMDN <i>CND code/ GMDN</i> | Z1302 / 15-639 | | |
| Finalidad Prevista <i>Intended Use</i> | Papel para electrodiagnóstico, su funcionalidad es el registro gráfico de señales bioeléctricas para la monitorización y diagnóstico, así como registro de datos y valores representativos. <i>Electrodiagnostic paper, its functionality is the graphic recording of bioelectric signals for monitoring and diagnosis, as well as data record and representative values.</i> | | |
| Clasificación: <i>Classification:</i> | Clase I (anexo VIII regla 1) <i>Class I</i> (annex VIII rule 1) | | |

Cumple con los requisitos generales de Seguridad y Funcionamiento y disposiciones de:
Conforms with the General Safety and Performance Requirements and provisions of:

Reglamento de Productos Sanitarios (UE) 2017/745, y sus modificaciones y las legislaciones nacionales adicionales / Medical Devices Regulation (EU) 2017/745 as amended and the additional national laws.

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| Ruta evaluación conformidad: <i>Conformity assessment route</i> | Anexo II - III Annex II - III |
| Documentación Técnica: <i>Technical documentation</i> | TF-001-PND |
| Sistema de Calidad según: <i>Quality System according:</i> | ISO 13485:2016. (n. 9124 PAEL) until 10.03.2026 por IMQ/CSQ ISO 9001:2015 (n.9120 PAES) until 10.03.2026 por IMQ/CSQ |

Barcelona 17/02/2023



Eduardo Fernández
Administrador / Manager

ANEXO I / ANNEX I
REFERENCIAS / REFERENCES:

| | | |
|---------|---------|---------|
| 0503700 | 1005720 | 1010608 |
| 0504400 | 1005721 | 1010803 |
| 0504401 | 1005722 | 1010900 |
| 0504402 | 1005723 | 1011001 |
| 0505701 | 1005724 | 1011002 |
| 0505702 | 1005725 | 1011004 |
| 0505705 | 1005726 | 1011005 |
| 0505800 | 1005800 | 1011006 |
| 0507000 | 1005801 | 1011009 |
| 0507500 | 1005804 | 1011010 |
| 0507600 | 1005805 | 1011014 |
| 0510001 | 1005807 | 1011018 |
| 0511400 | 1006000 | 1011019 |
| 0521500 | 1006001 | 1011021 |
| 1003700 | 1006003 | 1011023 |
| 1003702 | 1006014 | 1011024 |
| 1003703 | 1006031 | 1011025 |
| 1003704 | 1006201 | 1011027 |
| 1003705 | 1006304 | 1011101 |
| 1005008 | 1006307 | 1011200 |
| 1005011 | 1006309 | 1011206 |
| 1005012 | 1007000 | 1011211 |
| 1005019 | 1007500 | 1011212 |
| 1005029 | 1007501 | 1011218 |
| 1005039 | 1007503 | 1011219 |
| 1005045 | 1007800 | 1011220 |
| 1005047 | 1007801 | 1011400 |
| 1005049 | 1008000 | 1011401 |
| 1005502 | 1008001 | 1011402 |
| 1005504 | 1008002 | 1012002 |
| 1005701 | 1008004 | 1012003 |
| 1005703 | 1008006 | 1012011 |
| 1005704 | 1008007 | 1012012 |
| 1005706 | 1008008 | 1012600 |
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| 1005712 | 1008020 | 1021017 |
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| 1005715 | 1010402 | 1021502 |
| 1005716 | 1010600 | 1521000 |
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| 1005719 | 1010603 | 1521040 |
| | 1010606 | 1521060 |

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| 3011000 | |