

## 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-00000582

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

**Nombre** Papeles de registro médico.  
**Name** Recording charts for medical equipment

**Series: Ver anexo ./ REF See Annex**

**Marca** LESSA  
**Trademark** LESSA

**UDI-DI Básico** 84287631029PAPGRIDXF  
**Basic UDI-DI**

**Código CND/GMDN** Z1302 / 15-639  
**CND/GMDN code**

**Finalidad Prevista** 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.

**Intended Use** *Electrodiagnostic paper, its functionality is the graphic recording of bioelectric signals for monitoring and diagnosis, as well as data record and representative values.*

**Clasificación:** Clase I con función de medida (anexo IX en MDD regla 1)  
**Classification:** Class I with measuring function (annex IX MDD 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:**

RD 1591/2009 y Directiva Europea 93/42/CEE y sus modificaciones posteriores) / RD 1591/2009 and European Directive 93/42 / EEC and its subsequent modifications).

**Ruta evaluación conformidad:** Anexo II / Annex II  
**Conformity assessment route**

**Documentación Técnica:** TF-002-PD  
**Technical documentation**

**Certificado CE / ECCertificate:** 1349/MDD by IMQ SpA (NB 0051) until 01.07.2023

**Sistema de Calidad según:** ISO 13485:2016. (n. 9124 PAEL) until 10.03.2023 por IMQ/CSQ  
**Quality System according:** ISO 9001:2015 (n.9120 PAES) until 10.03.2023 por IMQ/CSQ

Barcelona 29/04/2021

Eduardo Fernández  
Administrador / Manager

## ANEXO I / ANNEX I

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**REFERENCIAS / REFERENCES:**

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