

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	Electrodos multifunción desechables para desfibrilación externa, cardioversión sincronizada, estimulación cardíaca y monitorización ECG	
Name	Disposable multifunction electrodes for external defibrillation, synchronized cardioversion, cardiac stimulation and ECG monitoring	
	Series: 99.835.	REF See Annex
Marca	LESSA DEFI-PAD	
Trademark	LESSA DEFI-PAD	
UDI-DI Básico	842876399835DEFIPADF2	
Basic UDI-DI		
Código CND/GMDN	C020401 / 15-033	
CND/GMDN code		
Finalidad Prevista	Electrodos multifunción desechables para desfibrilación externa, cardioversión sincronizada, estimulación cardíaca y monitorización ECG. Disponibles en tamaño adulto y pediátrico. Uso por personal adecuadamente formado.	
Intended Use	Disposable multifunction electrodes for external defibrillation, synchronized cardioversion, cardiac stimulation and ECG monitoring, affordable in adult and child size. To be used for adequately trained staff.	
Clasificación:	Clase IIb	(anexo IX en MDD regla 9)
Classification:	Class IIb	(annex IX MDD rule 9)

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-006-DP
Technical documentation	
Certificado CE / ECCertificate:	1143/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

REFERENCIAS / REFERENCES:

Referencia / Reference	Referencia / Reference	Referencia / Reference	Referencia / Reference
99.835.00	99.835.33	99.835.71R	99.835.91
99.835.01	99.835.34	99.835.72	99.835.92
99.835.02	99.835.36	99.835.72P	99.835.93
99.835.03	99.835.37	99.835.72PR	99.835.94
99.835.04	99.835.50	99.835.72R	99.835.95
99.835.04L2	99.835.50P	99.835.73	99.835.96
99.835.05	99.835.51	99.835.73P	99.835.97
99.835.06	99.835.51P	99.835.74	99.835.98
99.835.07	99.835.52	99.835.75	
99.835.08	99.835.52P	99.835.75P	
99.835.09	99.835.53	99.835.75R	
99.835.10	99.835.53P	99.835.76	
99.835.100	99.835.54	99.835.76P	
99.835.101	99.835.54P	99.835.77	
99.835.10A	99.835.55	99.835.77P	
99.835.11	99.835.55P	99.835.78	
99.835.12	99.835.56	99.835.79	
99.835.13	99.835.56P	99.835.80	
99.835.16	99.835.59	99.835.80U	
99.835.17	99.835.59P	99.835.83	
99.835.18	99.835.60	99.835.83P	
99.835.19	99.835.61	99.835.84	
99.835.22	99.835.61W	99.835.84P	
99.835.22U	99.835.62	99.835.85	
99.835.23	99.835.63	99.835.85P	
99.835.24	99.835.66	99.835.86	
99.835.25	99.835.66P	99.835.86W	
99.835.26	99.835.68	99.835.87	
99.835.27	99.835.70	99.835.87W	
99.835.28	99.835.70U	99.835.88	
99.835.30	99.835.71	99.835.89	
99.835.31	99.835.71P	99.835.90	