

DECLARACIÓN CE DE CONFORMIDAD EC DECLARATION OF CONFORMITY

Nombre del fabricante/
Manufacturer's Name:

AB MEDICA GROUP S.A

Dirección del fabricante/
Manufacturer's Address:

c/ Jericó, 10 Bis Interior. 08035 Barcelona. (ESP) España.

Dirección de fabricación/
Manufacturing site:

c/ Llobateras 14-18 Talleres 7. Nave 4 y 6. Polígono Industrial Santiga
08210 Barberà del Vallès. Barcelona. (ESP) España.

Almacén y Oficinas/
Warehouse and Offices:

Avda. Can Salvatella, 4. 08210 Barberà del Vallès. Barcelona (ESP)

Declara bajo su propia responsabilidad que el producto / *We declare under our own responsibility that the products:*

Nombre del producto/ Product name:

Papeles de registro médico
Recording charts for medical equipment

Referencias/References:

En anexo I
As per annex I

Clasificación (según Anexo IX en RD 1591/2009, Anexo VIII Reglamento 2017/745, en Directiva Europea 93/42/CEE y sus modificaciones posteriores) / Classification (According to Annex VIII f European Directives 93/42/EEC and subsequent amendments):

Clase I (con función de medida)
Class I (with measuring function)

GMDN 15-639

Los productos anteriormente mencionados se han fabricado en cumplimiento con los requisitos del Anexo II de la Directiva Europea 93/42/CEE y sus modificaciones posteriores, así como con los requisitos indicados en el Anexo II del RD 1591/2009 (transposición de la mencionada Directiva Europea y sus modificaciones posteriores a la legislación española). El certificado CE nº 1349/MDD emitido por el O.N. 0051 válido hasta el 01.07.2023 avala este cumplimiento. / *The above mentioned medical devices have been manufactured in compliance with the requirements in Annex II of the Council Directive 93/42/EEC, and subsequent amendments concerning medical devices. The EC Certificate nº 1349/MDD issued by the Notified Body Nbr. 0051 valid until 01.07.2023 supports the fulfillment.*

El Sistema de Calidad del fabricante cumple con los requisitos especificados por la norma ISO 13485:2016 quedando avalado por el certificado n. 9124.PAEL emitido por la entidad certificadora CSQ/IMQ. válido hasta el 10.03.2020/ *The fulfillment of the manufacturer's Quality Management System with the requirements of ISO 13485:2016 is supported by the certificate n. 9124.PAEL issued by the certification body CSQ/IMQ valid until 10.03.2020.*

Barberà del Vallès, 23 de Noviembre de 2018 / 23th Novembrer 2018

Eduardo Fernández
El Administrador/Manager

ANEXO I DE LA DECLARACIÓN DE CONFORMIDAD CE PAPEL DE REGISTRO MÉDICO

ANNEX I OF THE EC DECLARATION OF CONFORMITY FOR RECORDING CHARTS FOR MEDICAL EQUIPMENT

Referencias/Reference:

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