



Especialidades Médicas **Myr** S.L.



## EC Declaration of Conformity / *Declaración de Conformidad CE*

Manufacturer / *Fabricante*

**Especialidades Médicas MYR S.L.**

C/ Lleida 17-23 - 43712 Llorenç del Penedès - Tarragona - Spain

We declare under our own responsibility that the product / *Declaramos bajo nuestra responsabilidad que el producto*

### **Tissue Embedding Center EC 500 / *Centro de Inclusión EC 500***

meets all the requirements of the following European Directives that are applicable  
*cumple todos los requisitos aplicables de las siguientes Directivas Europeas*

|                    |                                                                                                                                                            |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>98/79/EC:</b>   | In Vitro Diagnostic Devices Directive<br>Classification: General IVD (Other), neither listed in Annex II of IVD 98/79/EC nor IVDs for self-testing purpose |
| <b>2014/30/EU:</b> | Electromagnetic Compatibility (EMC) Directive                                                                                                              |
| <b>2014/35/EU:</b> | Low Voltage Directive                                                                                                                                      |
| <b>2011/65/EU:</b> | Restriction of the Use of Hazardous Substances in electrical and electronic equipments (RoHS) Directive                                                    |

The product is designed and manufactured according to the relevant parts of the following International Standards  
*El producto está diseñado y fabricado de acuerdo con las partes relevantes de los siguientes estándares*

|                                    |                              |
|------------------------------------|------------------------------|
| <b>IEC 61010-1: 2010 + A1:2016</b> | <b>IEC 61010-2-010: 2014</b> |
| <b>IEC 61010-2-101: 2015</b>       | <b>EN 61326-1: 2013</b>      |
| <b>EN 61326-2-6: 2013</b>          | <b>EN ISO 14971: 2012</b>    |

In addition, the following standards are applied:

*Además, la empresa trabaja de acuerdo con las siguientes normas:*

|                        |                                             |
|------------------------|---------------------------------------------|
| <b>ISO 9001-2015:</b>  | Quality Management system                   |
| <b>ISO 13485-2016:</b> | Medical Devices - Quality Management system |

Llorenç del Penedès, 19/06/2019

**ESPECIALIDADES MÉDICAS MYR S.L.**

NIF: B-43202597

C/ Lleida, 17-23, Pol. Ind. L'Empalme  
43712 LLORENÇ DEL PENEDÈS - SPAIN

Tel: +34 977 668 030 - Fax: +34 977 668 030

**Francisco Ruiz Robles**  
Managing Director / *Director General*