Especialidades Médicas Myr S.L.

AENOR GESTIÓN CALIDAD PRODUCTOS SANITARIOS ISO 13485 GS-0002/2014

AENOR GESTIÓN DE LA CALIDAD ISO 9001 ER-0031/2014

IQNET LTD

EU Declaration of Conformity

We, Especialidades Médicas MYR S.L., with Single Registration Number ES-MF-000038831, registered office at Joaquín Costa, 2, 4º - 50001, Zaragoza – Zaragoza, Spain and factory at Lleida, 17-23 – 43712, Llorenç del Penedès – Tarragona, Spain, hereby declare under our sole responsibility that the medical device

Trademark:	**Myr**	
Trade Name:	**EC 500**	
Product:	**Modular Tissue Embedding Center**	
Modules:	EC 500-1: Cryo Console	
	EC 500-2: Dispensing Console	
	EC 500-3: Thermal Console	
Basic UDI-DI:	EC 500 (220-240V): 843701449710DW	EC 500-1 (220- 240V): 843701449711DY
	EC 500-2 (220-240V): 843701449712E2	EC 500-3 (220-240V): 843701449713E4
Risk Class:	A	
Product Description:	The EC 500 Embedding Center is a device for paraffin embedding of human tissue specimens previously infiltrated in paraffin and used for medical histological diagnosis by a pathologist.	

meets all the relevant parts of the following regulations and standards:

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011
- Commission Delegated Directive (EU) 2015/863 of 31 March 2015
- Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014
- EN 61010-1:2010 + AMD1:2019
- EN 61010-2-101:2017
- EN 61010-2-010:2014
- EN 61326-1:2013
- EN 61326-2-6:2013
- EN ISO 14971:2019

Our Quality Management System is certified according to ISO 9001: 2015 and ISO 13485: 2016.

This declaration is effective for products placed on the market as the date of issue. Any modification of the device not authorized by Especialidades Médicas Myr S.L. will invalidate this declaration.

Llorenç del Penedès, 17/05/2024

Francisco Ruiz Robles
Managing Director