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:	**MYREVA SS-30**	
	MYREVA SS-30H	
Product:	**Automated Slide Stainer**	
Basic UDI-DI:	SS-30: 843701449707E9	SS-30H: 843701449714E6
Risk Class:	A	
Product Description:	The SS30 slide stainer is an automatic device designed for the staining of human tissue specimens to contrast cell formations and their components for medical histological diagnostic purposes 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