ANMAT
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

"NEW CONSIDERATIONS FOR REGISTERING MEDICAL PRODUCTS PREVIOUSLY REGISTERED"

Medical devices registration holders shall apply for the registration on the Medical Devices Register, according to Regulation 5031/09.

To such end holders shall:

1. Apply for product registration under Regulation 2318/02, in compliance with the provisions of Regulation 5267/06.

http://www.anmat.gov.ar/tecmed/productos/productos.asp

2. Apply for medical product registration before the deadline set forth in Annex I of Regulation 5031/09 – according to the product relevant type of risk.

http://www.anmat.gov.ar/Legislacion/ProductosMedicos/Disposicion_ANMAT_5031-2009.pdf

3. Unify under a same number of Medical Device all those products previously registered which are effectively proved to belong to the same product family and produced by the same manufacturer(s).

http://www.anmat.gov.ar/productos_medicos/Observaciones_aplicables_Solicitudes_Inscripción_Familia_PM.pdf

Companies applying for the registration of medical devices which were previously registered under Regulation 2318/02 (TO 2004) and having the Certificate of Registration and Marketing Authorization of medical devices shall submit such ORIGINAL documents to ANMAT reception desk (ground floor) upon withdrawal of a certified copy of the regulation concerning registration and its annexes I, II and III.

Service of Equipment, devices and products,

Office of Medical Devices