

NOTIFICATION

Addendum

The following communication, dated January 26th 2018, is being circulated at the request of the Brazil Delegation.

Provides for the expiration date of the registration of medical devices.

The Draft Resolution n.º 371/2017, notified through G/TBT/N/BRA/730, was adopted as a final text, published as ANVISA Resolution – RDC nº 211, January 22nd, 2018.

It is established the period of ten (10) years for the validity of the registration of medical devices. This Resolution applies to medical devices within the scope of "correlates" referenced by Law Nº. 6,360, dated September 23, 1976.

The medical devices cover medical products and in vitro diagnostic products, as defined in Collegiate Board Resolution No. 185 of October 22, 2001 and Resolution of the Collegiate Board of Directors - RDC No. 36 of August 26, 2001.

The period of validity of registrations granted prior to publication of this Resolution are automatically extended to 10 (ten) years. Requests for revalidation of registration of medical devices filed up to the date of publication of this Resolution shall be terminated.

The full text is available only in Portuguese and can be downloaded at:

http://portal.anvisa.gov.br/documents/10181/3426501/RDC_211_2018_.pdf/086ee486-e958-4850-8ee7-06de5f3d84e0
