Technical Names of In Vitro Diagnostic Medical Devices (IVD) with Multiple Risk Classification Possibilities

The application of risk classification rules established in RDC No. 36/2015 and RDC No. 830/23 for in vitro diagnostic medical devices is governed by the intended purpose of the product declared in the instructions for use.

There are situations that direct the same parameter to different classification rules, such as the intended user (professional or lay use), use in neonatal screening, among others.

We emphasize the importance of verification by companies regarding the adequacy of the sanitary framework of their product portfolio, mainly due to the occurrence of technical names that may be associated with more than one risk class and subject to different regularization regimes.

To facilitate the identification of the most common situations linked to parameters with more than one risk class, the Management of In Vitro Diagnostic Products (GEVIT) has included a guidance term alongside the technical name of higher risk, with other situations possibly related to the classification.

We also emphasize that for technical names COMBINED PARAMETERS IN THE SAME PRODUCT, it is necessary to verify, in addition to the applicability of §4, art. 9 of RDC No. 830/23, which guides the association to the highest risk class if more than one classification rule applies, also the "List of technical names that will undergo sanitary reclassification" from 06/01/2024, the date on which RDC No. 830/23 comes into force.

When it is necessary to change the regularization regime due to a change in risk classification, the request must be made through the Solicita system, using subject 8420 IVD - Rectification - Correction by ANVISA for cases of sanitary risk reduction, and IVD - Sanitary Reclassification (80305

- for single product and 80306 - for products grouped in a family), if the change is directed to increased risk, i.e., from notification to registration.

New submissions must also observe the rules and intended uses of the products to ensure that the regularization request protocol is made using the appropriate petition subject.

Technical Names Table

Technical Name	Risk Class	Regime
17-HYDROXYPROGESTERONE (17-OHP)	II	Notification
17-HYDROXYPROGESTERONE (17-OHP) - NEONATAL SCREENING	III	Registration
AMINO ACIDS	II	Notification
AMINO ACIDS - NEONATAL SCREENING	III	Registration
ANTI-TSH RECEPTOR ANTIBODY (TRAb)	II	Notification
ANTI-TSH RECEPTOR ANTIBODY (TRAb) - NEONATAL SCREENING	III	Registration
BETA 2-MICROGLOBULIN	II	Notification
BETA 2-MICROGLOBULIN - TUMOR MARKER	III	Registration
HUMAN CHORIONIC GONADOTROPIN BETA (BHCG)	II	Notification
HUMAN CHORIONIC GONADOTROPIN BETA (BHCG) - TUMOR MARKER	III	Registration
KAPPA/LAMBDA CHAIN	II	Notification
KAPPA/LAMBDA CHAIN - TUMOR MARKER	III	Registration
CALCITONIN	II	Notification
CALCITONIN - TUMOR MARKER	III	Registration
DENGUE AND CHIKUNGUNYA	III	Registration
DENGUE AND CHIKUNGUNYA - BLOOD BANK	IV	Registration
GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD)	II	Notification
GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) - NEONATAL SCREENING	III	Registration
ENTEROCOCCUS	II	Notification
ENTEROCOCCUS FAECIUM	III	Registration
FREE ESTRIOL	II	Notification
FREE ESTRIOL - SCREENING FOR CONGENITAL DISORDERS	III	Registration
PLACENTAL GROWTH FACTOR	II	Notification
PLACENTAL GROWTH FACTOR (CONGENITAL DISORDERS)	III	Registration

Technical Name	Risk Class	Regime
FERRITIN	II	Notification
FERRITIN - TUMOR MARKER	III	Registration
GLUTAMATE DEHYDROGENASE (GDH)	II	Notification
GLUTAMATE DEHYDROGENASE (GDH) IN FECES - C. DIFFICILE	III	Registration
GALACTOSE	II	Notification
GALACTOSE - NEONATAL SCREENING	III	Registration
THYROID STIMULATING HORMONE (TSH)	II	Notification
THYROID STIMULATING HORMONE (TSH) - NEONATAL SCREENING	III	Registration
INHIBIN	II	Notification
INHIBIN - TUMOR MARKER	III	Registration
COMBINED PARAMETERS IN THE SAME PRODUCT - CLASS II	II	Notification
COMBINED PARAMETERS IN THE SAME PRODUCT - CLASS III	III	Registration
COMBINED PARAMETERS IN THE SAME PRODUCT - CLASS IV	IV	Registration
COMBINED PARAMETERS IN THE SAME PRODUCT (III) - NEONATAL SCREENING	III	Registration
COMBINED PARAMETERS IN THE SAME PRODUCT (IV) - NEONATAL SCREENING	IV	Registration
THYROGLOBULIN (TG)	II	Notification
THYROGLOBULIN (TG) - TUMOR MARKER	III	Registration
THYROXINE (T4)	II	Notification
THYROXINE (T4) - NEONATAL SCREENING	III	Registration
THYROXINE BINDING GLOBULIN (TBG)	II	Notification
THYROXINE BINDING GLOBULIN (TBG) - NEONATAL SCREENING	III	Registration
TRYPSIN	II	Notification
TRYPSIN (IRT) - NEONATAL SCREENING	III	Registration
YERSINIA SP	II	Notification

Technical Name	Risk Class	Regime
YERSINIA PESTIS	III	Registration

Revision History

Date	Revision History
03/22/2024	Initial issue
01/14/2025	Version 2 - Inclusion of Sanitary Reclassification subject codes in the 6th paragraph - Inclusion of technical names BETA 2-MICROGLOBULIN and BETA 2-MICROGLOBULIN - TUMOR MARKER - Inclusion of technical names ENTEROCOCCUS and ENTEROCOCCUS FAECIUM - Inclusion of technical names GLUTAMATE DEHYDROGENASE (GDH) and GLUTAMATE DEHYDROGENASE (GDH) IN FECES - C. DIFFICILE
04/14/2025	Version 3 - Exclusion of technical names C-REACTIVE PROTEIN and ULTRASENSITIVE C-REACTIVE PROTEIN (both are classified as class II) - see Technical Note No. 17/2025/SEI/GEVIT/GGTPS/DIRE3/ANVISA.
04/23/2025	Version 4 - Inclusion of technical names DENGUE AND CHIKUNGUNYA and DENGUE AND CHIKUNGUNYA - BLOOD BANK