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CERTIFICATE OF QUALITY ASSURANCE

Product name : ID DiaClon Rh subgroups + K
REF : 002124
LOT : 50110.29.01
Expiry date : 2018.03
Source of Material : monoclonal antibodies
Cell line of mAb : For more information, please refer to Instruction of Use
Composition : antibodies in buffered salt solution with
bovine albumin
preservative: < 0,1% NaN₃
Product presentation : ID-cards with gel suspension and antibody
Store at : 18-25°C

DiaMed GmbH is registered by the Swiss Governmental Authorities to produce in-vitro diagnostics for medical devices and is certified by the notified body, TÜV SÜD Product Service GmbH, for ISO 9001:2008 and EN ISO 13485:2003. The application of EN ISO 13485 ensures manufacturing quality of in-vitro diagnostics and all other medical devices and stays therefore in analogy to Good Manufacturing Practices (GMP). It is certified that the above product passed all tests for specificity and potency as required by the DiaMed Quality Control Product Release Specifications. Source materials from human origin from which the products were manufactured, were found non reactive for HIV 1/2, HCV and HbsAg when tested with licensed reagents.