DiaMed GmbH

Certificate of Analysis

Material Description:	ID-DiaClon Rh-subgroups+K 4x12
Material Number:	002124
Batch Number:	1646183603
Manufacture Date:	2017-08-11
Expiration Date:	2018-08-31

Product Code	50110
IHD Display Batch	501103603

For more information, please refer to IFU

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 13485:2012. 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 successfully all Quality Control analysis ensuring conformity with DiaMed GmbH release specifications.
Source materials from human origin from which the products were manufactured, were found non-reactive for anti-HIV 1/2, anti-HCV and HbsAg when tested with licensed reagents.
The above listed product is not the object of a market withdrawal from a Food and Drug Agency, or from other Worldwide Competent Authorities.

Francoise Buergy

This certificate has been verified and electronically approved by an authorized Quality representative.
This e-signature is performed within a secure system.

2017-08-22 / 04:57:47 UTC

Date/Time