

Certificate of Registration

In accordance with European Communities Council Directive 98/79/EC amended by 2011/100/EU 20th December 2011 concerning In Vitro Diagnostic Medical Devices as transposed into European national law by the member states

Certificate No.
SGP/2014/12/01

Certificate issue date;
1st January 2018

Certificate expiry date;
31st December 2018

We hereby declare that

- An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.
- The EU Authorised Representative contract has been fulfilled

And the  mark may be applied to the products listed below.

Organisation / Client:

Restalyst Pte Ltd
50 Loyang Way
Singapore
508743

Products:


FLU4PLEX-RAMP - EDMA Code: 15 30 02 42
HCC-REAAD™ IGFBP2 ELISA - EDMA Code: 12 06 04 04
NPC-REAAD™ EBV IgA EA Antibody ELISA - EDMA Code: 15 04 04 90
GC-REAAD ITIH3 ELISA - GMDN Code: 31445
MTB-RAMP – EDMA Code: 15 01 07 40

Competent Authority Information:

In Vitro Medical Device Directive registration is with the UK Medicines and Healthcare Regulatory Agency (MHRA) and the below registration has been issued.

IVD000947

Authorised Representative Labelling Information:

 Advena Ltd. Pure Offices, Plato Close, Warwick CV34 6WE UK.

Advena Limited.

Authorised Signature:



Registered office;

Pure Offices, Plato Close, Tachbrook Park
Warwick CV34 6WE. United Kingdom
Registered in England & Wales No. 3517275

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Email; info@advenamedical.com



This certificate is subject to the organisation maintaining their documentation in compliance with the regulations stated in this certificate.

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