

MEDICAL DEVICES

29 March 2021

MD027: Section 21 Authorisation for the Importation of Research Use Only (RUO) In Vitro Diagnostic Devices (IVDs)

INTRODUCTION

1. The Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, (“the Medicines Act”), read in conjunction with the Regulations relating to medical devices and in-vitro diagnostic medical devices (“the Medical Devices Regulations”), published in Government Gazette Notice 40480, No.1515 of 9 December 2016, provides for the regulatory oversight of medical devices including in- vitro diagnostics (IVDs) in South Africa.
2. **“Research use only”** (“RUO”) is defined in the regulations as “an IVD labelled for “research use only”, and “for investigational use only” and may not be used for clinical diagnostic purposes.
3. A RUO product may be an IVD device that is:
 - a. in the laboratory research phase of development; **or**
 - b. intended for use in the conduct of non-clinical laboratory research with goals other than the development of a commercial IVD product, i.e., these products are used to carry out research and are not themselves the object of the research.
4. RUO IVDs are neither used nor intended to be used for clinical diagnosis, or support thereof, of a clinical condition in a human or an animal.
5. An IVD device labelled for RUO is thus limited to use in the conduct of laboratory research that is either related or unrelated to the development of IVDs, providing instructions for correctly using the product in a research manner (for example, mixing proportions, incubation times, storage conditions, etc.) and is consistent with “research use only” labelling.
6. With respect to IVD products that are appropriately labelled RUO, the RUO classification and label serves as a warning, to prevent such products from use in clinical diagnosis or patient management.
7. In terms of Section 21 of the Medicines Act, the Authority may authorise the sale of unregistered medicines, medical devices or IVDs for certain purposes—
 - (1) *The Authority may in writing authorise any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine, medical device or IVD which is not registered.*

- (2) Any medicine, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.
- (3) The Authority may at any time by notice in writing withdraw any authority granted in terms of subsection (1) if effect is not given to any determination made in terms of subsection (2).
8. In terms of Regulation 3(3) of the Medical Device Regulations—
A person may only import a medical device or IVD if that person-
(a) is licensed in terms of section 22C(1)(b) of the Act to import medical devices or IVDs; and
(b) in the case of unregistered medical devices or IVDs, is authorised by the Council to import the unregistered medical devices or IVDs.
9. Authorisation for the import of an unregistered RUO IVD, in terms of Section 21 of the Medicines Act, will be issued by SAHPRA provided that the application meets the criteria set out below.

SUBMITTING A SECTION 21 APPLICATION FOR IMPORTATION OF RUO IVD

10. Any entity or person, located in South Africa, intending to conduct non-clinical laboratory research may submit a section 21 application to SAHPRA to import a RUO IVD.
11. An application form (refer **Annexure A**) for the purpose of obtaining the section 21 authorisation to import a Research Use Only (RUO) In Vitro Diagnostic (IVD) medical device in terms of the provisions of the Medicines Act read in conjunction with the Medical Device Regulations, must be submitted to SAHPRA.
12. The application must include the following attached documentation:
- Classification of the IVD in other jurisdictions recognised by SAHPRA; (Australia; Brazil, Canada; European Community; Japan; USA & WHO);
 - Product / component label(s) and kit label, where relevant;
 - Information for Use / User manual;
 - Proof of payment for a section 21 authorisation
13. Please ensure that on submission to the Authority all relevant fields are completed and all supporting documentation is attached. Incomplete applications will be identified as deficient and review will not be progressed until deficiencies are addressed.
14. The prescribed section 21 application fee and proof of payment must accompany the application. For the current fee payable, refer to the latest fee schedule as published in the Government Gazette and published on the SAHPRA website.
15. Payments should be made as per 17.05 “Guideline on the payment of fees to SAHPRA”, accessible here: <https://www.sahpra.org.za/wp-content/uploads/2021/01/SAHPRA-Payment-Guideline-Nov-2020.pdf>

16. The completed application should be submitted electronically to: mdadmin@sahpra.org.za

SECTION 21 CONDITIONS

17. Authorisation in terms of Section 21 may be provided subject to certain conditions including that:
 - a. the RUO IVD may only be used by the individual or entity specified in the application;
 - b. only the batch number of the RUO IVD and the quantity thereof specified in the application may be imported;
 - c. any other condition that the Authority may apply.
18. This process is not applicable to RUO IVDs that have previously been imported on a SAHPRA distributors licence, and will be applicable only for new applications for the importation of RUO IVDs.

TIMELINES FOR PROCESSING OF SECTION 21 RUO IVD APPLICATIONS

19. Applications will be processed within three weeks of receipt thereof.
20. An observation letter will be sent to the applicant in the event that an application does not meet the evaluation criteria. The deficiencies identified within the application will be documented in the observation letter.
21. The applicant is required to respond to the deficiencies noted in the observation letter **within five working days**.
NOTE: Only two cycles will be permitted, i.e. the applicant will have two opportunities to address deficiencies identified in the application by submitting a response to SAHPRA within the defined timelines.
22. If the response/s (limited to a maximum of two cycles) from the applicant does not adequately address the deficiencies identified in the application, the application will not be recommended and the application will be rejected.

DR B SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER OF SAHPRA
29 March 2021

ANNEXURE A

SECTION 21 RESEARCH USE ONLY IN-VITRO DIAGNOSTIC DEVICE (RUO IVD) APPLICATION

PART 1: GENERAL INFORMATION***Applicant***

Name: (Entity/ Person)	
Address:	
Contact person:	
Telephone no.:	
Cell no.:	
E-mail address:	
Date of application:	

PART 2: CHECKLIST -Documents Submitted with Application (Circle or shade applicable)

Cover letter date	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Application form	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Checklist completed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Information for Use/ User Manual	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Classification of the IVD in other jurisdictions recognised by SAHPRA	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Component, Kit and Packaging Label, where relevant	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Proof of Payment	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Signed declaration	<input type="checkbox"/> Yes	<input type="checkbox"/> No

PART 3: RESEARCH USE ONLY IVD INFORMATION TO BE PROVIDED

Name of product	
Original Manufacturer name:	
Address: (including country of origin)	
Intended purpose or use of the RUO IVD	
Quantity of RUO IVD required	
Batch Number of RUO IVD to be used	
Name and number of the model or type including software version and accessories (if any) to permit full identification	
Labelled with clause "For research use only"	

PART 4: RESEARCH/ STUDY

Name and Reference of Research/ Study	
Duration of the Research/ Study	
Planned start and stop date of the Research/ Study	
Name of Lead Investigator/ Research Scientist	
Contact Details of Lead Investigator/ Research Scientist	

PART 5: ADDITIONAL COMMENTS

Provide any additional information that may be relevant to the study

PART 6: DECLARATION

Applicants should note that in terms of the provisions of the Medicines and Related Substances Act 101, 1965 (Act 101 of 1965), it is an offence to make false and misleading statements

I declare that the intended use of the IVD is for RUO in the laboratory research phase of development or in the conduct of non-clinical laboratory research.

I declare that only the batch numbers and quantities specified in the application will be imported and used for the RUO studies.

I further declare that all information contained in this application form, and in the documents attached, is true and correct at the date of signing.

Signature of Authorised Person

Name

Date