World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 4546
Fax direct: +41 22 791 4836
E-mail: diagnostics@who.int

In reply please refer to: HA/sh

Your reference:

Meril Diagnostics Pvt. Ltd.
Attention: Mr K. Sridhar
Diagnostics
D1-D3, Meril Park, Survey no. 135/2/B & 174/2
Muktanand Marg, Chala
Vapi
396191
Inde

29 September 2023

WHO Prequalification Programme
WHO Prequalification of In Vitro Diagnostics
Change Request Decision Letter

Change Request Number: PQC-IVDR-2023-0044
Date submitted: 7 February 2023
Product Name: MERISCREEN HIV 1-2 WB
Manufacturer name: Meril Diagnostics Pvt. Ltd.
Application Number: PQDx 0464-074-00

Summary of changes

The manufacturer submitted a change request *"1. Addition of one pack size with new product code to the existing pack sizes i.e., 25 Tests (HVWRPD-09)*
2. Addition of new pack sizes with Auto safety lancet viz., 30 Tests (HVWRPD-10), 60 Tests (HVWRPD-11) and 40 tests HVWRPD-12)".

Decision

☒WHO approves the implementation of this change as described in the assessed documents. The change has been accepted.
☐WHO does not approve the implementation of this change. The change has been rejected.
☐Decision pending upon availability of additional data. Please refer to Annex A, below.

Rounds of additional information

☒ N/A

If you have any questions, please do not hesitate to contact us by email (diagnostics@who.int) or by telephone (+41 22 791 4546).

Digitally signed by Poiata Vitalie
Date: 2024.01.17 13:01:11 EET
Reason: MoldSign Signature
Location: Moldova

Yours sincerely,

Dr Fatima Gruszka
Technical Officer
In Vitro Diagnostics Assessment Team
Prequalification Unit
Regulation and Prequalification Department

Annex A - Summary Report

Evidence Provided for the Change	Findings and requests	Issue Closed Y/N/NA
1. Description of the change and rationale	The proposed change as well as its motivation were properly described in the documents "2 Detailed Description of Planned Changes" and "3 Attachment 3 Reasons for the change".	Y
2. Timelines of implementation	Change affects product configurations (number of tests) and kit components (new lancet) and is expected to be implemented right after approval.	NA
3. Change control procedure	The documentation provided indicate that the change has been properly handled so, although SOP was not provided nor referenced in the documents presented, the manufacturer appears to have a change control SOP in place, when all supporting documentation, including QMS certificates, supplier control, QC records and verification studies are considered.	Y
4. Risk management report	The risk assessment of addition of new pack sizes and new auto safety lancets has been considered in the risk management report as evidenced on page 21, 56 and 108 of the risk management report provided in the document "2 - Risk Management Report HIV RAPID_Rev 17".	Y
5. Risks at each stage of the product lifecycle	The risk management procedure, applicable to whole product lifecycle, appears to be functional, as in the documents provided in the folder "5.5 Risk Management Plan and Report".	Y
6. Document control	The responsible person in indicated in the change form. All supporting QMS documents provided are properly signed.	Y
7. Change control plan	Refer to item 3.	
8. Validation	Refer to item 3. The manufacturer conducted studies to verify the test performance using the new auto safety lancets as presented in the study report provided in the document "Performance Validation study report of Manual lancet and auto (safety) lancet".	Y
9. Validation report	The incoming inspection test report templates and COAs applicable to the new safety lancets introduced were provided in the documents listed below, located in the folder named as "11.2 CoA and Test Report Manual and Auto". • COA_Auto lancet 2 • Test Report_Auto lancet 2_PM221612 • COA_Auto lancet 1 • Test Report_Auto lancet 1	Y

10. Information on changed processes and procedures	Incoming inspection for the new kit component (auto safety lancets) appears to be in place as evidenced above.	Y
11. Quality control process	The applicable sampling plan for the inspection of new components is referenced in the incoming inspection test report templates provided in the documents "Test Report_Auto lancet 2_PM221612" and "Test Report_Auto lancet 1".	Y
12. Sampling plan	The new kit configurations and respective product codes are described in Table 1 (p. 1) of the document "2 Detailed Description of Planned Changes". The new auto safety lancet suppliers and related approval records were provided in the folder "11.3 AutoSafety Lancet Suppliers Docs".	Y
13. Product description	Although the SOP for supplier control was not provided, it appears to be functional, as the evidence provided in the records section below.	Y
14. Supplier control procedure	The supplier evaluation and approval records for the auto safety lancets were provided in the documents "Supplier Approval & Registration Form Medtrue" and "Supplier Registration and approval form" (Tianjin Rilifine Medical Device Co., Ltd). The supplier's QMS certificates and other supporting documents were also provided in the folder "11.3 AutoSafety Lancet Suppliers Docs".	Y
15. Supplier qualification/approval report	The COA for the new safety lancets were provided in the documents listed below located in "11.2 CoA and Test Report Manual and Auto" folder. • COA_Auto lancet 1 • COA_Auto lancet 2 The lancet key specifications, including sterilization status, are described in the COAs provided. Sterilization method is not described in COA of Auto Lancet 1 (From Tianjin) but it can be found in the actual internal inspection template provided ("Test Report_Auto lancet 1").	Y
16. Certificates of analysis	ISO 13485 certificates were provided for both lancet's suppliers in the folder "11.3 AutoSafety Lancet Suppliers Docs".	Y
17. Certification of suppliers/manufacturers	The lancet from "Medtrue" are CE marked (MDD), as in the certificate issued by TUV SUD provided in the document "CE certificate Medtrue.pdf", valid until 2024-05-26. The lancet from "Tianjin Rilifine Medical Device Co. Ltd" holds a US FDA 510k approval (K222055) as in the file "USFDA_K222055.Letter.SE.FINAL_Sent001". The approval was also confirmed in US FDA 510k database on 14/AUG/2023.	Y
18. Valid product approval certificates	The sterility claim for the new lancets was found in the respective COAs provided by the suppliers as well as in internal incoming inspection documents from the manufacturers, as presented in the folder "11.2 CoA and Test Report Manual and Auto".	Y

	Special process (sterilization) is presumed to have been evaluated during routine QMS audits. Both suppliers are ISO 13485 certified and have been qualified by the manufacturer.	
19. special processes and related products certification	The impact of the change on test performance was verified by comparing the results of the assay using the current "manual" and the new safety lancets introduced in the kit, as in the study report "Performance Validation study report of Manual lancet and auto (safety) lancet" provided in the folder "11.1 Performance Validation Study".	Y
20. Performance evaluation	A full performance assessment is not deemed to be necessary, as the change does not impact specimen type, specimen volume and/or relevant reagents.	NA
21. Potential impact on the test performance assessed	Not applicable.	NA
22. Study protocols	Not applicable.	NA
23. Compliance with WHO guidance and applicable specifications	Not applicable.	NA
24. Reference method/comparator	Not applicable.	NA
25. Sample types supporting evidence	Not applicable.	NA
26. Reports or summary of reports of the studies	The IFU and labels for the new kit configurations were provided in the folder "8-9 Labels and Pack Insert".	Y
27. Labeling and Instructions for use	Not applicable.	NA
28. Training information updates	Not applicable.	NA
29. PMS process updates	Not applicable.	NA
Overall Conclusion	The Manufacturer has provided sufficient evidence to support the change, the change request is accepted with no need of further requests.	**Y**