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In reply please refer to: P5-447/KR/SL

Your reference:

Matthew Wang
Dermacare Biosciences
(Suzhou) Medical Supply Co., Ltd.
Authorized agent for the manufacturer
Room 210, Building 5, No.77 Jinsigang Road,
Guoxiang Street, Wuzhong District, Suzhou
苏州市金丝港路77号方泰科技园5幢210

24 November 2020

Dear Mr Wang,

OUTCOME OF DESK ASSESSMENT
EUL Emergency Use Listing
WHO Prequalification Unit – Inspection Services
Dermacare Biosciences

Thank you for your email correspondence dated 12 October 2020 and the documents that were sent to the WHO PQT: Inspections Team for the Emergency Use Listing of SARS-CoV-2 (EUL) desk assessment of the Quality Management System of Dermacare Biosciences (Suzhou) Medical Supply Co., Ltd., *the Authorized agent for the manufacturer*. Kindly be advised that your application for a desk assessment was reviewed as described in the desk assessment report (enclosed). These related to the site, indicated as:

Name: Dermacare Biosciences (Suzhou) Medical Supply Co., Ltd.
Address: Room 210, Building 5, No.77 Jinsigang Road,
Guoxiang Street, Wuzhong District, Suzhou

The documents submitted for the desk assessment were found to be satisfactory and are considered to constitute adequate evidence of compliance with ISO 13485 and the requirements described in the “*Instructions and requirements for Emergency Use Listing (EUL) submission: In vitro diagnostics detecting SARS-CoV-2 nucleic acid and rapid diagnostics tests detecting SARS-CoV-2 antigens (PQDx_347 version 4; 09 June 2020)*”.

Furthermore, this desk assessment allows Prequalification Inspection Team to recommend to the Prequalification Assessment Team that the site may be named as a manufacturing site in the dossier for the following product:

PQT Number	Product
EUL 0582-223-00	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Please do not hesitate to send an email to prequalinspections@who.int should you require any further information regarding the closure of this inspection.

Yours sincerely,

Dr Joey Gouws
Team Lead, Inspection Services
Prequalification Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division