

MGK

40, Dongmadong-ro 43beon-gil, Haseong-myeon, Gimpo-si, GYEONGGIDO, 10012, KOREA, REPUBLIC OF

is registered and has listed the following medical device with the U.S. Food and Drug Administration for FY 2021 pursuant to Title 21, CFR Part 807 of the United States Code of Federal Regulations

Owner/Operator Number: 10079537

D-U-N-S Number: **695126363**

Premarket Submission Number: 510(K) Exempt

Device Listing Number: **D429202**

Proprietary Name: CMT CHECK-19 PATCH

Device Classification Name: THERMOMETER, CLINICAL COLOR

CHANGE

Product Code: FOZ

Device Class: Class 1

Expiration Date: December 11, 2020 ~ December 31, 2021

BSC Korea Co.,Ltd. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. BSC Korea Co.,Ltd. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. BSC Korea Co.,Ltd. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 cfr 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. BSC KOREA Co., Ltd.. is not affiliated with the U.S. Food and Drug Administration.



Jacho, Kim

Executive Director

BSC Korea Co.,Ltd.

Dated: December 11, 2020