

No.: ICR Polska/DR/HS240112

Applicant: GANZHOU SANMEI INDUSTRY AND TRADE CO. , LTD.

address: 308 Binjiang Road, Lianjiang town, Xingguo County Ganzhou City, Jiangxi Province, China

Manufacturer: GANZHOU SANMEI INDUSTRY AND TRADE CO. , LTD.
308 Binjiang Road, Lianjiang town, Xingguo County Ganzhou City, Jiangxi Province, China

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Regulation (EU) 2017/745 Annexes II & III

Product: Hot Cold Compress Gel Ice Packs

Model(s): H08187, H08188, H08189, H08190, H08191, H08192, H08193, H08194, H08195, H08196, H08197, H08198, H08199, H08200, H08201, H08202, H08203, H08204, H08205, H08206, H08207, H08208, H08209, H08210, H08211, H08212, H08213, H08214, H08215, H08216, H08217, H08218, H08219, H08220, H08221, H08222, H08223, H08224, H08225, H08226, H08227, H08228, H08229, H08230, H08231, H08232, H08233, H08234, H08235, H08236, H08237, H08238, H08239, H08240, H08241, H08242, H08243, H08244, H08245, H08246, H08247, H08248, H08249, H08250

Product trademark: n/a

Declared classification: Class I (Not Sterile according to the Manufacturer's declaration – does not require the participation of a NB)

Technical Documentation: TMJX24010454048
prepared by GANZHOU SANMEI INDUSTRY AND TRADE CO. , LTD.

Date of review: 09.01.2024

Expiration date: 08.01.2029

Review output:

- This document was issued voluntarily and at the request of the applicant.
- The above-mentioned Technical Documentation provided to us by the applicant is compatible in terms of the general requirements for the documentation of this type of product, but its scope of review is not equivalent to Notified Body assessment and such shall be carried independently.
- The manufacturer is responsible for the CE marking process and is not exempt from carrying out all necessary activities related to the legal compliance.



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A handwritten signature in blue ink, appearing to be "Rafał Kalinowski".

Director: Rafał Kalinowski

