DOCUMENTATION REVIEW

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S/N: 007430

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 compatibile 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.

International Certification ICR Registrar Ltd.

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