

Documentation Review



No. 3Q210414.QATUQ63

Holder: Qingdao Aiwa Tech. Ltd.
No.9, Feihang Road, Tianzhuang Town, Pingdu,
Qingdao City, Shandong Province

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Regulation 2017/745 Annex I

Product: Disposable Heated Blanket (Heated Vest)

Model(s): QHV1, QHP2, QHP4, QHP6, QHP8, QHP9, QHP10, QHP12, QHP14

Classification: Class I (Not Sterile according to the Manufacturer's declaration – therefore not requiring NB intervention.)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 14 April 2021

Approver
ECM Service Director
Luca Redonni



Expiry date 13 April 2026

Technical Expert
Amanda Payne

