Review Report –审查报告–검토 보고서– Rapport d'Evaluation

Documentation Review

No. 5T211118.HHHCD29

Holder: Hebei Houde Hanfang Medical Devices Group Co., Ltd.
Beisun Village, Zhengding County, Shijiazhuang City, Hebei Province, China

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

Product: HEALTH PATCH

Model(s): *(see the following annex)*

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.
Technical documentation identified with the no. TST202111Q2165-1SR dated 2021.11.16
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 18 November 2021

Approver
ECM Service Director
Luca Redonni

Expiry date 17 November 2026

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