

S/N: 003416

No.: ICR Polska/VC/HM220934

Applicant: ZHANGJIAGANG CONGCONG RUBBER AND PLASTIC PRODUCT PACKING FACTORY

address: Heniwan, Xincheng Village, Jingang Town, Zhangjiagang City, Jiangsu Province, China

Manufacturer: ZHANGJIAGANG CONGCONG RUBBER AND PLASTIC PRODUCT PACKING FACTORY
Heniwan, Xincheng Village, Jingang Town, Zhangjiagang City, Jiangsu Province, China

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

Product: Medical rescue and rehabilitation system

Model(s): GD-01, GD-02, GDH-1A6A, GDH-1A6B, GDH-1A6C, GDH-1A6D, GDH-1A6E, GDH-1A6F, GDH-1A6G, GDH-1A6M, GD-03), GD-17, GDH-4A/B/C, GDH-4D, GDH-1F1, GDH-1GL, GHD-1C, GDH-1D, GDH-1DL, GDH-5A/B/C, GDH-3A, GDH-3B, GDH-3E, GDH-8B, GDH-1A6L, GDH-6A, GDH-6B, GDH-6D, GDH-4E, GDH-7H, GHD-7N, GDH-7D, GDH-8A/B, GDH-9/10, GDH-AS01, GDS-01, GDS-02, GDS-03, GDS-04, GDS-05, GDS-06, GDS-07, GDH-as-03, GDH-320, GDH-1A/1C, GDH-rt1/rt2, GDH-15

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: TCF220916-026MDR
prepared by
ZHANGJIAGANG CONGCONG RUBBER AND PLASTIC PRODUCT PACKING FACTORY

Date of review: 19.09.2022

Expiration date: 18.09.2027

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 read "Rafał Kalinowski".

Director: Rafał Kalinowski

