

## DOCUMENTATION REVIEW

S/N: 006737

## No.: ICR Polska/DR/HM231111

Applicant: Shandong Sogood Hygiene Product Co.,Ltd

address: 59 Huihe Road, Dongying District, Dongying City, Shandong Province, China

Manufacturer: Shandong Sogood Hygiene Product Co.,Ltd

59 Huihe Road, Dongying District, Dongying City, Shandong Province, China

Review goal: Verification of the presence of Technical Documentation compatible with the Medical

Devices Regulation (EU) 2017/745 Annexes II & III

Product: Disposable Underpad,

Adult Diaper, Adult pull-up pants, Baby Diaper, Baby pull-up pants

Model(s): XS, S, M, L, XL, XXL, XXXL

Product trademark: n/a

Declared Class I (Not Sterile according to the Manufacturer's declaration – does not require the

classification: participation of a NB)

Technical ZBB07231020109

Documentation: prepared by Shandong Sogood Hygiene Product Co.,Ltd

Date of review: 03.11.2023 Expiration date 02.11.2028

## **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.



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