

No.: ICR Polska/DR/HM231085

Applicant: Shandong Yabin Medical Technology Co., Ltd

address: No. 203 weisi road, Qilu chemical industrial park, Linzi district, Zibo city, Shandong, China, 255410

Manufacturer: Shandong Yabin Medical Technology Co., Ltd
No. 203 weisi road, Qilu chemical industrial park, Linzi district, Zibo city, Shandong, China, 255410

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

Product: Low Temperature Thermoplastic Products

Model(s): Y-M001, Y-M001-02, Y-M001-03, Y-M001-04, Y-M001-05, Y-M002, Y-M002-02, Y-M002-03, Y-M002-04, Y-M002-05, Y-M002-06, Y-M002-07, Y-M003, Y-M003-02, Y-M003-03, Y-M003-04, Y-M003-05, Y-M003-06, Y-M003-07, Y-M003-08, Y-M003-09, Y-M003-10, Y-X001, Y-X001-02, Y-X002, Y-X002-02, Y-X002-03, Y-X002-04, Y-X003, Y-X003-02, Y-X003-03, Y-AT06, Y-AT06-02, Y-AT06-03, Y-F001, Y-F001-02, Y-F001-03, Y-F001-04, Y-F002, Y-AJ08, Y-AJ08-02, Y-AJ08-03, Y-WJ10, Y-WJ10-02, Y-WJ10-03, Y-WJ10-04, Y-WJ10-05, Y-FLB, Y-KB, Y-PB, Y-BMB, Y-GN001(S), Y-GN001(M), Y-GN001(L), Y-GN002(S), Y-GN002(M), Y-GN002(L), Y-GN005(S), Y-GN005(M), Y-GN005(L), Y-W1.6, Y-W2.0, Y-W2.4, Y-W3.2, Y-W4.0, Y-K1.6, Y-K2.4, Y-K3.2, Y-K4.0, Y-GS001, Y-GM002, Y-GM003, Y-GW004, Y-GW005, Y-GM006, Y-GM007, Y-GW008, Y-GS009, Y-GS10, Y-GW11, Y-GH12, Y-GZ13, Y-GX14, Y-GZ15, Y-GH16, Y-GX17, Y-GH18, Y-GF001, Y-GF002, Y-GF003, Y-GF01-02.

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: ZYY20231026MDR01
prepared by Shandong Yabin Medical Technology Co., Ltd

Date of review: 30.10.2023

Expiration date: 29.10.2028

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 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.



ICR Polska Co. Ltd.
www.icrpolska.com
icrpolska@icrq.com

Director: Rafał Kalinowski

