DOCUMENTATION REVIEW

S/N: 002850

No.: ICR Polska/DR/HS220509

Applicant:	Yiwu Wenmei Import & Export Co., Ltd
address:	7th Building 7. No.788 Cheng Dian South Road, Yiwu city, ZheJiang, China
Manufacturer:	Yiwu Wenmei Import & Export Co., Ltd 7th Building 7. No.788 Cheng Dian South Road, Yiwu city, ZheJiang, China
Review goal:	Verification of the presence of Technical Documentation compatible with the Medical Devices Regulation (EU) 2017/745 Annexes II & III
Product:	Plastic Cartridge Needle
Model(s):	EN1, EN2, EN3, EN4, EN5, EN6,
Product trademark:	EMALLA
Declared classification:	Class I
Technical Documentation:	PCNTCF0530-MDR prepared by Yiwu Wenmei Import & Export Co., Ltd
Date of review:	31.05.2022
Expiration date	30.05.2027

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 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.

International Certification ICR Registrar Ltd.

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