EU Declaration of Conformity

DOC-CE2026-IVDR018-MM-01

Manufacturer Info.	Maccura Medical Instrument Co., Ltd. Building 4, 8# 2nd Anhe Road, Hi-tech Zone, 611731 Chengdu, PEOPLE'S REPUBLIC OF CHINA
Manufacturer SRN	CN-MF-000028087
European Representative Info.	Humiss International B.V. Joop Geesinkweg 701, 1114 AB Amsterdam-Duivendrecht, the Netherlands
EU-REP SRN	NL-AR-000001490
Notified Body	TÜV SÜD Product Service GmbH Ridlerstraße 65 • 80339 Munich • Germany
Basic UDI-DI	697216835200019R
EMDN Code	W0202010102
Notified Body ID No.	0123
Product Name	Automatic Hematology Analyzer
Models	F 880, F 810, F 800
Certificate No.	V13 091353 0012 Rev.00
Valid From	2026-04-23
Valid Until	2031-04-22
Conformity Assessment Procedure	Annex IX Chapter I and III of Regulation (EU) 2017/746
Classification	Class B , Rule 6 (Annex VIII)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Regulation (EU) 2017/746 on in vitro diagnostic medical devices.
All supporting documentation is retained at the premise of the manufacturer.

Applicable Regulation	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices
CS	Not applicable
Standards	EN ISO 13485: 2016 EN ISO 18113-1:2011 EN 13612: 2002 EN ISO 14971: 2019 EN ISO 18113-2:2011 EN 62366-1:2015 EN ISO 15223-1:2021 EN 62304:2006 + A1:2015 EN IEC 61010:2010+A1:2019 EN IEC 61010-2-101:2022+A11:2022 EN IEC 61326-1:2021 EN IEC 61326-2-6:2021
Start of CE-MARK	2026-04-23
Place,Date of issue	Chengdu, 2026-04-23
Signature	You Li *Function: Person Responsibility for Regulatory Compliance*

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Annex

Intended Purpose

This product is used in conjunction with the reagents of Maccura Biotechnology Co., Ltd., based on the automated method to quantitatively detection the formation of human whole blood, micro whole blood, pre-diluted blood and body fluids, and complete blood cell count, white blood cell five-differential, humoral cell measurement, hemoglobin concentration measurement, and reticulocyte measurement. In order to achieve the purpose of monitoring and aiding in the diagnosis of inflammation, anaemia, etc. This product is intended for all populations and is used by medical professionals in the laboratory environment.

Note:

1. The F 800 only exclude reticulocyte measurements detection item, and the rest of the measurement items and principles are the same as other models.
2. Body fluid sample types include cerebro-spinal fluid, serous cavity effusion, synovial fluid; Do not use the instrument to test unsupported sample types.

Product Code

IVR code 0608
IVS code 1008/1010
IVP code 3006
IVD code 4005
IVT code 2010/2011

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