DOC-CE2023-213-MI-03

Declaration of Conformity

Manufacturer Address	Maccura Medical Instrument Co., Ltd. Building 4, 8# 2nd Anhe Road, Hi-tech Zone, 611731 Chengdu, PEOPLE'S REPUBLIC OF CHINA.
European Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product Information	Automatic Hematology Analyzer (Model: F 560, F 560L, F 560S, F 580, F 580L, F 580S)
Classification	Other device (all devices except Annex II and self-testing devices)
Conformity Assessment Route	Annex III, except section 6

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Council DIRECTIVE 98/79/EC on in vitro diagnostic medical devices.
All supporting documentation is retained at the premise of the manufacturer.

General Applicable Directive	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
Start of CE-MARK	2018-05-03
Place, Date of issue	Chengdu, 2023-06-16
Signature	汪雯 General Manager

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