DOC-CE2023-319-MI-02

Declaration of Conformity

Manufacturer	Maccura Medical Instrument Co., Ltd.
Address	A area 2nd Floor Building 6, 1st and 5th~7th Floor Building 5, 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 880, F 880S, F 810, F 810S, F 800, F 800S)
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	2020-12-31
Place, Date of issue	Chengdu,2023-03-24
Signature	General Manager

CE

maccura