

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)
Eiffelstrasse 780, 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

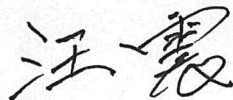
*We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Council DIRECTIVE 98/79/EC on in vitro diagnostic medical devices.
All supporting documentation is retained at the premise of the manufacturer.*

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



General Manager



maccura