dewei

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Date: 2023.08.11 11:51:53 EEST
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Declaration of Conformity

CE

Manufacturer:
DEWEI MEDICAL EQUIPMENT CO.,LTD
5th floor, No. 4 building, Shiyou Industrial Park, Jun'an, Shunde, Foshan, China 528329

European Representative:
MedNet GmbH
Borkstrasse 10, 48463 Muenster, Germany

Product Name: Hematology Analyzer
Analyte: Whole Blood, Prediluted Blood.

Model: DW-3680, DW-3690, DW-36VET, DW-5680, DW-5690

Classification:
According to directive 98/79/EC: Others devices
Conformity Assessment Route: IVDD 98/79/EC Annex III
We the manufacturer herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the premises of the manufacturer.

The products comply with the essential requirements in accordance with In Vitro Diagnostic Directive 98/79/EEC.

General applicable directive:
Directive 98/79/EC

Standards Applied:
ISO 13485:2016 ISO9001: 2008 EN ISO14971: 2012
EN13612: 2002 EN13640: 2002 EN ISO 18113-1:2011
EN ISO 18113-2:2011 EN 62366:2008 IVDD 98/79/EC

First Start of CE-MARK: Apr.16, 2021

Signature: Managing Director Cai Daidi

DEWEI MEDICAL EQUIPMENT CO.,LTD
佛山市顺德区德维医疗科技有限公司

Place, Date of Issue: Foshan, Apr.16, 2021

Dewei Medical Equipment Co.,Ltd