DECLARATION OF CONFORMITY

ACCORDING TO In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Device Classification

Classification: Class A.

Rule: According to Rule 5, Annex VIII, of In Vitro Diagnostic Medical Devices Regulation (EU)2017/746.

Applicable Standards

EN ISO 20417: 2021,
EN ISO 15223-1:2021,
EN ISO 18113-1:2011,
EN ISO 14971:2019,
EN ISO 18113-2:2011

Manufacturer

Name: B&E BIO-TECHNOLOGY CO., LTD.
Address: No.11 Jieaisi Road,Laishan District,Yantai City, Shandong Province, P.R. China

Product Information

Name : Calibration pack for Electrolyte Analyzer
Model : Medica EasyLyte、AVL9180、CBS-300、CBS-400、CBS-500、CBS-301、CBS-401、CBS-501、CBS-3、CBS-4、CBS-5、KS-401
EMDN : W010103
Basic UDI-DI :
Classification: Class A

Conformity Assessment

Compliance of the designated product with the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 has been assessed by issuing the EU declaration of conformity referred to in Article 17 after drawing up the technical documentation set out in Annexes II and III.

Remark

The declaration of conformity is valid in connection with the release technical document CE/IVDR-W010103-07.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Declaration

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 and the applicable standards above.

Signature: Date: Mar 10, 2022

Position: GM Place: Shandong/China