



Bioevopeak Co., Ltd.

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DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully Regulation (EU) 2017/746 on in vitro diagnostic medical devices have been taken as reference for these processes

Company Name: Bioevopeak Co., Ltd.
Brand: BIOEVOPEAK
Related Directives and Annex: Regulation (EU) 2017/746 on in vitro diagnostic medical devices
Related Standards: EN 61326-1:2013; EN 61010-1:2010
Product(s): Auto Hematology Analyzer
Type(s)/Model(s): HEMA-D6031;HEMA-D6190;HEMA-D6130;HEMA-D6051;
HEMA-D6052;HEMA-B6051Mini;
Parameters: 220V,50 Hz
Classification: Laboratory Equipment
Examination Period: July 28, 2022
Date of Expiry: July 27, 2027
Review Result: We, Bioevopeak Co., Ltd.declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices was detected.

Year of DOC marking: **2022**

Signed for and on behalf of

Company: Bioevopeak Co., Ltd.

General Manager: 

Document No: BEPSD-220728001

