

CELAB®

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CERTIFICATE

Certificate Number **UCN** : **802497389091**

Job : J27439

Date of Issue : 2019-09-09

Certificate valid up to : 2023-09-08

Brand Name : See Label

Type : Automatic chemistry analyzer

Model N : BK-1200, BK-800, BK-600, BK-500, BK-400, BK-280, BK-200, BK-200mini

Manufacturer : Biobase Biodustry(Shandong) Co., Ltd

Address : Biobase Industry Park, Crossing of Jingshi East Road and Mingbu Road,
Mingshui Economic Development Zone, Zhangqiu, Jinan City Shandong Province, China

Standard Used : EN 60601-1:2006+A1:2013


Conclusion :

After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:

93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .

The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✓ OK
Presence of test report using standards as indicated in the declaration of conformity	✓ OK
Test report reference : ESC-BBBS-2019-09-1C	
Presence of  symbol in the product label.	✓ OK
Presence of instruction manual	✓ OK
Use of valid Harmonized standard in the declaration of conformity	✓ OK
Presence of product description in the technical construction file	✓ OK

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Massimiliano Bertoldi
General Manager – CELAB
www.celab.com

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