BIOBASE

Biobase Biodustry (Shandong) 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

Medical Devices Directive 93/42/EEC has been taken as reference for these processes

Company Name:

Biobase Biodustry (Shandong) Co., Ltd.

No. 51 South Gongye Road, Jinan, Shandong Province, China

Examination Intent:

Examination the completeness of the Technical Documentation

according to the requirements of Annex II excluding section 4

(Module H) of 93/42/EEC

Harmonised Standards:

EN1041:2008; EN ISO 10993-1: 2009; N 60601-1: 2006; EN 60601-

1-2: 2015; EN ISO 13485: 2016; EN ISO 15223-1: 2016

Product(s):

Drying Oven

Type(s)/Model(s):

BOV-T25F, BOV-T50F, BOV-T105F, BOV-T200F, BOV-V30F, BOV-V35F,

BOV-V45F, BOV-V65F, BOV-V70F, BOV-V125F, BOV-V136F, BOV-

V225F, BOV-V230F

Classification:

I (according to the classification rules of the MDD)

Examination Period:

March 26, 2019

Date of Expiry:

March 25, 2024

Review Result:

We, Biobase Biodustry (Shandong) Co., Ltd, declare that during the selftesting and performance evaluation, no Non-compliance according to

the requirements of Annex II excluding section 4 (Module H) of

93/42/EEC has been detected.

Year of DOC marking: 2019

Signed for and on behalf of

Company:

Biobase Biodustry (Shandong) Co., Ltd.

ISHANDO

General Manager:

Document No:

MDD-1903264

