BIOBASE

ADD: No.51 South Gongye Road, Jinan, China250100
TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

EC DECLARATION OF CONFORMITY

We, **Biobase Biodustry (Shandong) Co., Ltd,**
No. 51 South Gongye Road, Jinan City, Shandong Province, P.R. China

herewith declare that the blow mentioned product meets the provisions of the **Council Directive 93/42/EEC** for Medical Device Directive (MDD). All supporting documention is retained under these premises and/or the premises of manufacture's subcontractors.

Product Name: **Pressure Steam Autoclave**

Model: **BKM-Z18N, BKM-Z24N, BKM-Z16B, BKM-Z18B, BKM-Z24B, BKM-Z18B(III), BKM-Z24B(III), BKM-Z45B(III), BKM-Z60B(III), BKM-Z80B(III), BKM-Z24S, BKM-Z45S, BKM-Z80S, BKQ-Z30I, BKQ-Z50I, BKQ-Z75I, BKQ-Z100I, BKQ-B50(II), BKQ-B75(II), BKQ-B100(II), BKQ-B120(II), BKQ-B150(II), BKQ-B200(II), BKQ-B50V, BKQ-B75V, BKQ-H150, BKQ-H200, BKQ-H300, BKQ-H400, BKQ-H500, BKQ-B100(H), BKQ-B150(H), BKQ-B200(H), BKQ-B300(H), BKQ-Z100(H), BKQ-Z150(H), BKQ-Z200(H), BKQ-Z300(H)**

Classification: **IIb** (according to classification rules in Annex IX of 93/42/EEC)

GMDN: **Sterilizer, moist heat, fluid / 41450**

Conformity Assessment Rout: Annex II excluding section 4(Module H)

Relevant harmonised standards: see the attachment

This DECLARATION OF CONFORMITY is valid in connection with the release document for the respective serial of produced devices.

The DECLARATION OF CONFORMITY is only valid in connection with a batch specific Certificate of compliance for the above products concerned bearing the CE mark.

Date of CE marking: April 18, 2019

Signed for and on behalf of
Company: **Biobase Biodustry (Shandong) Co., Ltd.**

General Manager: Robert Wang

Document No: BKMDD-190418

CE

Digitally signed by Grabazei Alexandru
Date: 2023.08.28 11:49:09 EEST
Reason: MoldSign Signature
Location: Moldova

ADD: No.51 South Gongye Road, Jinan, China250100
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Attachment

For
the Relevant Harmonised Standards

Standard	Title
EN 13060:2014	Small steam sterilizers
EN 14180:2003+A2:2009	Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing
EN ISO 13485:2016 EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 60601-1-1:2001	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems