

**E C DECLARATION OF CONFORMITY****Date of Issue 10-09-2017; Latest Update 05-05-2022****PRODUCT IDENTIFICATION**

Product Description	Model/Part Number
A active thermally insulated personal insulin cooler box designed to hold insulin or medical products safety at ready-use temperatures. Cooling is supplied by battery or chargeable.	Insulin Cooler box/BD8014

MANUFACTURER

Company Name	Address	Representative
Badu(xiamen) Technology Co., Ltd.	69,DONGDU ROAD,XIAMEN AREA OF CHINA(FUJIAN)PILOT FREE TRADE ZONE 361013	Ms. ERICA QIU, Export Manager.

CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards
Class 1, MDD 93/42/EEC: Article 9, Classification. Annex IX, Classification Criteria	MDD 93/42/EEC, Annex VII, EC Declaration of Conformity.	EN 724:1995 EN 46001:1997 EN ISO 11197-2009 EN 1041:2008+A1:2013 EN ISO 14971:2001 ISO 20282-1-2006 IEC 60529

REGISTRATION INFORMATION

Notified Body	CE Certificate Number	CE Marking First Applied
Not Applicable to Class 1 Devices (MDD 93/42/EEC, Article 11, Section 5)	Not Applicable to Class 1 Devices (MDD 93/42/EEC, Annex VII)	18 May, 2013

QUALITY MANAGEMENT SYSTEM

Issuing Authority	Certificate Number	Valid Until	Level of Compliance
China Quality Certification	00113Q212226R1S/3200	9 July, 2023	ISO 9001:2008
Centre (www.cqc.com.cn)			GB/T 19001-2008

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We hereby declare under our sole responsibility that:

the product described herein conforms with all the relevant provisions of the Council of European Communities Directive 93/42/EEC, Medical Devices for a Class 1 Device;

Harmonized Standards, to the extent that they apply, have been consulted to check conformity;

where Harmonized Standards do not apply, International Standards, to the extent that they apply, have been consulted;

National Standards have not been applied;

the Technical File required by the Directive 93/42/EEC in respect of the product described herein is maintained at the Registered Address of the Manufacturer, and is available from the Authorised Representative of the Company; and

this Declaration is made in accordance with the EC Directive 93/42/EEC, Annex VII, EC Declaration of Conformity.

THIS DECLARATION consists of two pages, and is made on behalf of Badu(Xiamen) Technology Co., Ltd. by:

Mr. QIU YOUNG

Managing Director & Legal Representative



Signature:

Date: 05 June, 2022