EU Declaration of Conformity

Legal Manufacturer

- Name - Address - Phone / fax / email / webpage	ABENA A/S Egelund 35 DK-6200 Aabenraa Denmark	www.abena.com Phone: +45 7431 1818 Fax: +45 7462 9737 Mail: info@abena.com
- Single Registration Number (SRN)	DK-MF-000002482	

Medical Device(s)

- Basic UDI-DI	Please see appendix I
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Please see appendix I
- Other ref. allowing identification (e.g. UDI-DI)	Please see appendix I
- Intended Purpose	Please see appendix I
- Risk classification	Class I according to rule no. 1 in MDR annex II

Other information (if applicable)

- Common Specifications used for compliance	ISO 13485:2016
- Notified Body name and identification no. and description of the conformity assessment procedure performed	N/A
- Additional information	N/A
- Standards used to assure compliance	Please see appendix II

The above mention manufacturer hereby declare that the above mentioned medical device(s) are compliant with the EU Regulation 2017/745 for Medical Devices and the EU legislations mentioned under "additional information".

This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

Name and Function:
Ane Kirstine Schmidt, Category Manager

Signature

Abena, Egelund 35, DK-6200 Aabenraa

Place and date of issue
Aabenraa, DK, 01.06.2021

EU Declaration of Conformity

Appendix I, List of products

Product Name	Item no.	Basic UDI-DI	Intended Purpose
Medical face mask with elastic ear loops, type IIR	1000010123	57035380FacMD-00I-06008SE	The medical face mask are intended to be used in medical settings, to protect the patient from infective agents and the wearer against splashes of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.
Medical face mask ties, type IIR	1000010124		
Medical face mask with elastic ear loops, type IIR	1999903629		
Medical face mask with elastic ear loops, type IIR	1999902619		
Medical face mask with ties, type II	220898	57035380FacMD-00I-06007SC	The medical face mask are intended to be used in medical settings, to protect the patient from infective agents. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.
Medical face mask with elastic ear loops, type II	220899		

expand list accordingly

Appendix II, List of applicable standards used

Product Name	Standards used
All products listed in Appendix 1	MDR EU 2017/745
	ENISO 14971:2019
	ISO10993-1:2018
	ISO10993-5:2009
	ISO10993-10:2013
	DS/EN 1041 + A1:2013
	ENISO15223-1:2016
	EN14683:2019+AC:2019
	expand list accordingly

EU Declaration of Conformity

EC Declaration of Conformity

Manufacturer:

Company name: Crown Name Disposable Hygiene Products Fty., Ltd.
Address: Chengbei Industrial Zone, Zhucheng Avenue, Xinzhou District., Wuhan City, Hubei China.
Tel: +86-27-83838228

Whose Authorized Representative:

Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the product

Product Name	Medical Device	Device Class	Model	UMDN
Disposable medical face mask(non-sterile) with earloops	Masks	I, Rule1 (Annex VIII of MDR)	1000010123	12447

meets the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745

Applicable Standards:

ISO 13485:2016
ENISO 10993-5: 2009
EN 1041:2008
ISO 14971:2019
ENISO 10993-10: 2013
ENISO 15223-1:2016
ISO 10993-1: 2018
EN14683:2019+AC:2019

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Basic UDI-DI: To be applied

SRN: To be applied

Name of authorized signatory: Dong fang Xu

Signature: 徐东方

Position held in the company: Management representative

Date: 2021.01.13

Place: Hubei, China

Crown Name Disposable Hygiene Products Fty., Ltd.

Seal/Stamp:

Declaration of Conformity

NO.:ZDYL/QSMDR-43

1. **Manufacturer:**

   Name: Zhende Medical Co., Ltd

   Address: Gaobu Town, 312035, Shaoxing, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

   SRN: The application of SRN is in process now

2. **European Representative:**

   Name: Shanghai international Holding Corp.GmbH(Europe)

   Address: Eiffestraße 80, 20537 Hamburg, Germany.

3. **Product Name:** Medical Mask（Type I / TypeII / TypeIIR）

   Basic UDI-DI: 69593857MM000001T8

Sold/marketed under the names: Medical mask, Medical face mask, Face mask with earloops

Tested under the name: ZD Type IIR face mask

REF	Specification	Type
1000010123	17cm*18cm-3P 50 pieces/box	Type IIR
1000010124	17cm*18cm-3P 50 pieces/box	Type IIR
1010001693	17cm*18cm-3P 80 pieces/box	Type IIR
1999902619	17cm*18cm-3P 150 pieces/box	Type IIR

4. **GMDN Code:** 35177
5. **Intended use:** Medical Mask is intended to cover the user's nose and mouth and provides a physical barrier to fluids and particulate materials.
6. **Classification:** class I non-sterile

   Based on MDR EU2017/745 Annex VIII Rule 1,

   All non-invasive devices are classified as Class I, unless one of the rules set out hereinafter applies

7. **Statement:**

   We declare the compliance of the above medical device with the applicable requirements of Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices. The EU declaration of conformity is issued under the sole responsibility of Zhende Medical Co., Ltd.

8. **CS:** NA
9. **Standard Applied:**

   EN ISO 15223-1:2016 EN 1041:2008+A1:2013 EN ISO 13485:2016

   EN ISO 14971:2019 EN 14683:2019+AC:2019

CE

Place and Date of Issue: Shaoxing, Zhejiang, 2021.03.16

Signature: Chen Ming

Name: Chen Ming

Position: Regulatory Director