



## EU Declaration of Conformity



According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

### Manufacturer

**Name:** Ningbo Albert Novosino Co., Ltd.

**Address:** No.1 Xinheng 3 Road, Cicheng Town Jiangbei District, 315036 Ningbo, Zhejiang China

**Trademark:** N.A.

### European Authorized Representative

**Name:** Humiss International B.V.

**Address:** Joop Geesinkweg 701, 1114 AB Amsterdam-Duivendrecht, the Netherlands

**SRN:** NL-AR-000001490

**Tel:** +31 (0)20 369 8116      **Fax:** +31 (0) 20 369 8114      **E-mail:** ce-tech@humiss.com

**SRN:** CN-MF-000008571      **Trade name:** Ear Syringe      **Product Name:** Ear Syringe

**Product code/Catalogue number:** ES1,ES2,ES3,ES4,ES5,ES6,ES7,ES8,ES9

**Basic UDI-DI:** 697191946ES4Z      **UMDNS Code:** 11-376

**Classification (acc. MDR, Annex VIII):** Class I , Rules 1      **CE certificate No.:** N.A.

**Name and ID of the Notified Body:** N.A.

We hereby declare under our sole responsibility that the class I medical devices listed above are in conformity with the general safety and performance requirements which apply (Annex I of the European Union Medical Device Regulation 2017/745). All supporting documentations are retained under the premises of the manufacturer.

This declaration is made in accordance with Annex IV of the European Union Medical Device Regulation 2017/745 and is valid for an undetermined period of time.

I, Jorome Zhang, hereby declare that the equipment specified above conforms to MDR 2017/745.

### Regulation:

EU MDR 2017/745

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

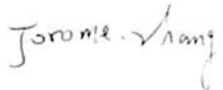
### Applicable Standards:

EN ISO13485: 2016    EN ISO14971: 2019    EN ISO 15223-1: 2016    EN ISO10993-1: 2020

EN ISO10993-5: 2009    EN ISO10993-10: 2013    EN 1041:2008+A1:2013    EN 62366-1:2015

**Name of the authorized person:** Jorome Zhang

**Position:** Corporate Representative

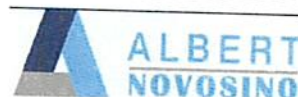
**Signature:** 

**Date:** June 29, 2021

宁波洛孚医疗科技有限公司  
Ningbo Albert Novosino Co., Ltd.

# Declaration of Conformity

*Ningbo Albert Novosino Co.,Ltd.*



## EU-Declaration of Conformity

### For CE-Mark Certification

We, the company *Ningbo Albert Novosino Co.,Ltd.* herewith declare, that the medical products described below:

- Nasal Aspirator
- Ear Syringe
- Breast Pump
- Rectal Syringe
- Vaginal Douche
- Enema kit
- Pump Bulb
- Air Cushion
- Ice Bag
- Hot Water Bottle
- Pressure Infusion Bag
- Blood Pressure Cuff

are specified as class I, paragraph VII products.

They are relating to appendix I, paragraph 7.1-7.6 of the EU-Guideline 93/42 EWG, these products meet the technical requirements of CE-Mark Certification.

Our Quality Management System is certificated according DIN EN ISO 9001:2008 and FDA certification.

*Gordon Hu*

宁波洛孚纳克塑业有限公司  
Ningbo Albert Novosino co., Ltd.



*Ningbo Albert Novosino Co.,Ltd.*

*No.1 Xinheng 3 Road Cicheng Town, Jiangbei District, 315036 Ningbo, Zhejiang, China*

*Tel:+86 574 87527883 Fax:+86 574 87527880*

# Finess Healthcare Group Co.,Ltd

Email: vicky@finess-healthcare.com Tel:86-574-27835863 Fax:86-574-27835986

## Declaration of Conformity

Manufacturer:	<b>Finess Healthcare Group Co.,Ltd</b> No.1503 A1 Block, No.203 Lantian Road 315000 Ningbo PEOPLE'S REPUBLIC OF CHINA
European Representative:	<b>ZOUSTECH S.L.</b> Pso. Castellana, 141-Planta 19, 28046-Madrid, SPAIN
Product Name	Plastic urine bottle, irrigator set, frog splint, washing syringe,
UMDNS-Code:	N/A

Classification (MDD, Annex IX): Class I Rule 1  
Conformity Assessment Route: **Annex VII**


We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Manufacturer takes full responsibility of the content of Declaration of Conformity.

### DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Signature: 

Name: *Honglang Li*

Place & Date: *Ningbo / 2018-2-24*

Position: **General Manager**