

## EU Declaration of Conformity

*Manufacturer:*

ZOGEAR Medical Co.,Ltd.  
Add:No.166, Industrial Concentration Area, Dayi Town,  
Yizheng City, Jiangsu Province  
Office: Room 2007, Building 2, No 2157, Hunan Rd., Sh  
anghai, China

*whose single Authorized EU-Representative:*

Luxus Lebenswelt GmbH  
Kochstr.1, 47877, Willich, Germany  
DIMID: DE/0000047791  
Tel: 0049- 1715605732  
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products:

### Surgical Aspirator Tips

Model:

TA004-1 ,TA004-2,TA004-3

meet the provisions of Regulation 2017/745/EU MDR which apply to them.

The medical device has been assigned to class I according to Annex IV of the Regulation 2017/745/EU MDR. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex IV of Regulation 2017/745/EU MDR.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

SRN No: CN-MF-000012353

UDI -DI code :

697484312TA004-1EE;

697484312TA004-2EG;

697484312TA004-3EJ

Applied Standards:

EN ISO13485:2016;EN ISO 15223-1:2016;EN 1041:2008+A1: 2013;ISO 14971:2019;ISO 10993-1:2018;  
EN ISO 10993-5:2009;EN ISO 10993-10:2013;IEC 62366-1:2015;EN ISO 14644-1:2015;EN ISO 14644-2:2015;EN  
ISO 14698-1:2003;EN ISO 14698-2:2003

The above mentioned declaration of conformity is exclusively under the responsibility of

ZOGEAR Medical Co.,Ltd.  
Add:No.166, Industrial Concentration Area,  
Dayi Town, Yizheng City, Jiangsu Province  
Office: Room 2007, Building 2, No 2157,  
Hunan Rd., Shanghai, China

Shanghai,China 2021/9/27



\_\_\_\_\_  
*Place, date*

\_\_\_\_\_  
*Legally binding signature, Function*