



## DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

### EU Representative

SUNGO Europe B.V.  
Olympisch Stadion 24, 1076DE  
Amsterdam, Netherlands  
SRN: NL-AR-000000247

### Conformity Assessment

Conformity Assessment Procedure  
Annex II+III of Regulation (EU) 2017/745

Applicable Standards  
EN ISO 14971: 2019  
EN ISO 15223-1: 2016  
EN 1041:2008+A1:2013  
ISO 10993-1: 2018  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-KR-05.*

*All the supporting documentation is retained at the premises of the manufacturer.*

*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.*

### Manufacturer

Name: Ningbo KeRui Hygiene Product Co., Ltd  
Address: Lihuaqiao Village, Shounan street, Yinzhou Zone, Ningbo, China

### Product Information

Name: Oral Swabs  
Model: 1). ridge size foam head, 2). quincunx size foam head, 3) Hexagon size foam head or customization  
GMDN: 48037  
Basic UDI-DI: /  
Classification: Class I

### Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: *Rui Hu*

Date: *2021-5-17*

Position: GM

Place: Ningbo

