



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: 2012
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-HR-01.

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.

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.



Authorized Signature (S)

Manufacturer

Name: WUJIANG HIPRO MEDICAL PRODUCTS CO., LTD.

Address: Zhenze Town, Suzhou City, Jiangsu Province, China

Product Information

Name: Cotton Tipped Applicators

Model: 150*2.2*5mm, 150*4*10mm, 100*4*10mm, 75*2.2*5mm, 200*2.2*5mm, 200*3*10mm

GMDN: 33722

Basic UDI-DI: 697463580CTP1906TQ

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:

Date:

Position: GM

Place: JiangSu



2021.03.17