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

Manufacturer

Name: Shandong Chengwu Medical Products Factory
Address: Southern End of Quancheng Road, Chengwu County, 274200 Heze City, Shandong Province, P.R.China.

Conformity Assessment

Conformity Assessment Procedure
Annex I+II+III, Article 19+Annex IV.

Applicable Standards
EN ISO 14971:2019
EN ISO 15223-1:2016
EN 1041:2008+A1:2013

Product Information

Name: Specimen Collection Swab
Model: S1,S2,S3,S4
GMDN: 57940
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.

Remark

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

Signature: Wang Jicun

Position: GM

Date:2021.03.10

Place:Shandong, China

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

Sungo global service

Authorized Signature (S)