

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
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: 2021
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Q010201-01.

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.

Manufacturer

Name: BEIJING OKVD BIOLOGICAL TECHNOLOGY LTD.
Address: 101, 1st to 3rd floors, Building 1, Yard 5,
Dasheng Road, Shunyi District, Beijing (north side of
1st floor)
SRN:

Product Information

Name: VPS Impression Material
Model: AK-Y-1×200m10; AK-Y-1×300m10; AK-Y-1×400m10;
AK-Y-1×500m10; AK-Y-1C×200m10; AK-Y-1C×300m10; AK-Y-1C
×400m10; AK-Y-1C×500m10; AK-Y-2×25m13; AK-Y-2C×25m13;
AK-Y-ATF×360m13; AK-Y-ATF×380m13; AK-Y-ATF×400m13;

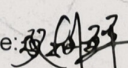
EMDN: Q010201

Basic UDI-DI: /

Classification: Class I, According to Rule 5, Annex
VIII, Regulation (EU) 2017/745

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: 2023.11.22

Position: GM

Place: Beijing/China

