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-Q010280-02.

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: Tray Adhesive
Model: AK-TA10ml
EMDN: Q010280
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: [signature] Date: 2023.11.22

Position: GM Place: Beijing/China

北京奥凯迪生物科技有限公司
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