

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: YingTai (Suzhou) Medical Technology Co., LTD.
No. 390, Yongjin Road, Miaoqiao, Tangqiao Town, Zhangjiagang
City, Jiangsu Province, China.

Trademark: N.A.

SRN: CN-MF-000038233

European Representative: Luxus lebenswelt GmbH
Kochstr.1,47877, Willich, Germany

SRN: DE-AR-000005110

Trade name: Surgical Drapes

Product Name: Surgical Drapes

CND Code: T020101

Basic UDI: 697423093PD001D3

Classification acc. to MDR Ax. VIII: Class Is , rule 1 of MDR Annex VIII

Intended Use It is intended to cover the patient's surgical skin around the wound surface, reducing the migration of the source of infection from the patient's surgical wound surface to the surgical wound site, and preventing postoperative wound infection.

General Specifications Non

Applied Standard & Common Specification: EN 13795-1:2025, EN ISO13485:2016/A11:2021, ISO11135:2014 + Amd.1:2018,ISO 11737-1:2018+Amd.1:2021, ISO 10993-5:2009, ISO10993-10:2021, ISO 10993-23:2021 + Amd.1:2025,EN ISO 14971:2019/A11:2021,EN 10993:2020,EN ISO 20417:2021,EN ISO 15223-1:2021,EN ISO 11607-1:2019,EN ISO 22610:2018.

Conformity assessment procedure: Annex XI, MDR (2017/745)

CE certificate No.: DZ 2104059-1

Name and ID of the Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Notified Body number : 0197



We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Place, date

320582201