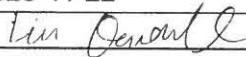


## EU Declaration of Conformity

|   |  |             |            |
|---|--|-------------|------------|
| Manufacturer:   | Name: Jiangsu Vedkang Medical Science and Technology Co., Ltd.<br>Address: No.52, Guoxiang Road, Wujin Economic Development Zone, Changzhou, 213149 Jiangsu, P.R.China<br>SRN: CN-MF-000008462 |             |            |
| Authorised Representative:  | Name: Shanghai International Holding Corp. GmbH (Europe)<br>Address: Eiffestrasse 80, 20537 Hamburg, Germany<br>SRN: DE-AR-000000001   |             |            |
| Products:   | Disposable Endoscopic Submucosal Dissection Knife  |             |            |
| Basic UDI-DI  | See Appendix I   |             |            |
| Model:  | See Appendix I   |             |            |
| EMDN Code:  | K020101  |             |            |
| Risk Class:   | IIb  |             |            |
| Classification Rule:  | Rule 9, Sub-clause 1, No indent, Annex VIII, (EU) 2017/745   |             |            |
| Conformity assessment Route:  | Annex IX Chapter I, Section 2 and 3<br>Medical Device Regulation (EU) 2017/745   |             |            |
| We, the manufacturer, herewith declare that the above-mentioned device(s) is (are) in conformity with the Regulation (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. All supporting documentation is retained at the premises of the manufacturer. This Declaration of Conformity is issued under the sole responsibility of the manufacturer. |  |             |            |
| Applicable Standards:   | All applicable harmonized standards are shown in the technical documentation "List of Applied / Harmonized Standards".   |             |            |
| Intended Purpose  | MONO- AND BIPOLAR DEVICES, SINGLE-USE<br>MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE  |             |            |
| Notified Body:  | Name: TÜV Rheinland LGA Products GmbH<br>Identification Number: CE 0197  |             |            |
| (EC) Certificate(s):  | HZ 2156843-1   | Valid until | 2028-11-21 |
| Start of CE-marking:  | 2023-11-22   |             |            |
| Signature:  | <br>Name: Liu Quanle<br>Function: Person responsible for regulatory compliance                              |             |            |
| Place, Date of Issue:   | Changzhou, P.R.China 2023-11-22  |             |            |

**Appendix I: Models for Disposable Endoscopic Submucosal Dissection Knife**

| No. | Models           | Basic UDI-DI   |                |
|-----|------------------|----------------|----------------|
| 1   | VDK-KM-40-160-TN | 697005757010H7 |                |
| 2   | VDK-KM-40-165-TN |                |                |
| 3   | VDK-KM-40-160-T  | 697005757063HU |                |
| 4   | VDK-KM-40-165-T  |                |                |
| 5   | VDK-KM-45-160-J  | 697005757008HL |                |
| 6   | VDK-KM-45-165-J  |                |                |
| 7   | VDK-KM-45-160-H  | 697005757009HN |                |
| 8   | VDK-KM-45-165-H  |                |                |
| 9   | VDK-KM-45-195-H  |                |                |
| 10  | VDK-KM-45-200-H  |                |                |
| 11  | VDK-KM-45-220-H  |                |                |
| 12  | VDK-KM-45-230-H  |                |                |
| 13  | VDK-KM-20-160-DN |                | 697005757011H9 |
| 14  | VDK-KM-20-165-DN |                |                |
| 15  | VDK-KM-15-195-DN |                |                |
| 16  | VDK-KM-15-200-DN |                |                |
| 17  | VDK-KM-15-220-DN |                |                |
| 18  | VDK-KM-15-230-DN |                |                |
| 19  | VDK-KM-20-160-D  | 697005757064HW |                |
| 20  | VDK-KM-20-165-D  |                |                |
| 21  | VDK-KM-15-195-D  |                |                |
| 22  | VDK-KM-15-200-D  |                |                |
| 23  | VDK-KM-15-220-D  |                |                |
| 24  | VDK-KM-15-230-D  |                |                |

End