

# DECLARATION OF CONFORMITY

CE 0197

We (Manufacturer's name) Zhejiang Medstar Technology Co., Ltd.

(Address) 1/F, Bldg.1, No.239 Yatai Rd., Nanhu District, Jiaxing City, 314050 Zhejiang, China

DECLARE that the conformity assessment of sanitary products,  
Open-surgery electrosurgical handpieces as follows manufactured in our factory

PS07 Standard smoke evacuation handpiece  
PS17 Standard smoke evacuation handpiece  
PS09 Telescopic smoke evacuation handpiece  
PS11 Telescopic smoke evacuation handpiece with lock  
PS18 Telescopic smoke evacuation handpiece with lock  
PS28 Telescopic smoke evacuation handpiece with lock

Along with accessories :

P-F Filter for handpiece P-FT Fluid trap for handpiece  
ESE-TS Tubing set for handpiece ESE-CN Connector for handpiece

Please refer to Annex I for detailed descriptions

Product Classification : Class IIb

GMDN Code: 61869

GMDN Term: Open-surgery electrosurgical handpiece/electrode

Latex-free : Yes DEP-free : Yes DEHP-free : Yes

浙江迈德实达医疗科技有限公司  
ZHEJIANG MEDSTAR TECHNOLOGY CO., LTD.

comply with

**Directive 93/42/EEC Annex II excluding Section 4**

**Directive 2011/65/EU including the delegated Directive 2015/863/EU**

as well as quality management systems

**EN ISO 13485:2016**

Notified Body : TUV Rheinland LGA Products GmbH

Certificate Registration No. : 60127756 0001 Expiry Date : 2028-12-31

Authorized Representative in EU : Obelis S.A.

Address : Boulevard General Wahis 53 1030 Brussels, BELGIUM

Tel: +(32) 2.732.59.54 Fax: +(32) 2.732.60.03 E-Mail : mail@obelis.net

We therefore assure the absence any endangering of the health and safety of persons, provided the that product is used for its envisaged purpose, as well as offering the qualities assigned to it. UNDERTAKES to establish and to keep up to date a systematic procedure to review the experience acquired with the production the phase after production, using the opportune means to apply the necessary corrective measures, and also UNDERTAKES to inform the competent authorities as to the following situations as soon as they become known:

- Any defective functioning or alteration of the characteristics of its features, as well as any inadequacy of the labeling or instructions for the use of the product which could give rise to or may have caused death or severe alteration of the state of health of a patient or of a user.
- Any technical or sanitary reason, related with the characteristics or the features of a product, for the reasons indicated in the previous paragraph which may have led the manufacturer to systematically withdraw products of the same type from the market.

(Place and date of Issue)

ZHEJIANG, CHINA

APR 01 2023

(Valid Until)

DEC 31 2028

(Authorized person)



| <b>Annex I, Part1</b>  |  |
|--|--|
| <b>Smoke Evacuation Handpiece</b>  |  |
| <b>Including non-sterile supplied products with"-NS" attached to the REF</b> |  |
| PS07-K70   | PS07 Smoke evacuation Handpiece, 70mm S/S Blade electrode, 3m cable, 3m tubing                   |
| PS07-K70L  | PS07 Smoke evacuation Handpiece, 70mm S/S Blade electrode, 5m cable, 3m tubing                   |
| PS07-K70L2   | PS07 Smoke evacuation Handpiece, 70mm S/S Blade electrode, 5m cable, 4.5m tubing                 |
| PS07-K70GY   | PS07 Smoke evacuation Handpiece, 70mm Non-stick Blade electrode, 3m cable, 3m tubing             |
| 57525641   | PS07 Smoke evacuation Handpiece, 70mm Non-stick Blade electrode, 3m cable, 3m tubing             |
| PS07-K70GYL  | PS07 Smoke evacuation Handpiece, 70mm Non-stick Blade electrode, 5m cable, 3m tubing             |
| PS07-K70GYL2   | PS07 Smoke evacuation Handpiece, 70mm Non-stick Blade electrode, 5m cable, 4.5m tubing           |
| PS07-K2X   | PS07 Smoke evacuation Handpiece, 70mm+152mm S/S Blade electrode, 3m cable, 3m tubing             |
| PS07-K2XGY   | PS07 Smoke evacuation Handpiece, 70mm+152mm Non-stick Blade electrode, 3m cable, 3m tubing       |
| PS07-K3X   | PS07 Smoke evacuation Handpiece, 70mm+100mm+152mm S/S Blade electrode, 3m cable, 3m tubing       |
| PS07-K3XGY   | PS07 Smoke evacuation Handpiece, 70mm+100mm+152mm Non-stick Blade electrode, 3m cable, 3m tubing |
| 57525646   | PS07 Smoke evacuation Handpiece, 70mm+100mm+152mm Non-stick Blade electrode, 3m cable, 3m tubing |
| PS07-G01   | PS07 Smoke evacuation Handpiece, 35mm nozzle, 3m cable, 3m tubing                                |
| PS07-G02   | PS07 Smoke evacuation Handpiece, 83mm nozzle, 3m cable, 3m tubing                                |
| PS17-K70   | PS17 Smoke evacuation Handpiece, 70mm S/S Blade electrode, 3m cable, 3m tubing                   |
| PS17-K70L  | PS17 Smoke evacuation Handpiece, 70mm S/S Blade electrode, 5m cable, 3m tubing                   |
| PS17-K70L2   | PS17 Smoke evacuation Handpiece, 70mm S/S Blade electrode, 5m cable, 4.5m tubing                 |
| PS17-K70GY   | PS17 Smoke evacuation Handpiece, 70mm Non-stick Blade electrode, 3m cable, 3m tubing             |
| PS17-K70GYL  | PS17 Smoke evacuation Handpiece, 70mm Non-stick Blade electrode, 5m cable, 3m tubing             |
| PS17-K70GYL2   | PS17 Smoke evacuation Handpiece, 70mm Non-stick Blade electrode, 5m cable, 4.5m tubing           |
| PS17-K2X   | PS17 Smoke evacuation Handpiece, 70mm+152mm S/S Blade electrode, 3m cable, 3m tubing             |
| PS17-K2XGY   | PS17 Smoke evacuation Handpiece, 70mm+152mm Non-stick Blade electrode, 3m cable, 3m tubing       |
| PS17-K3X   | PS17 Smoke evacuation Handpiece, 70mm+100mm+152mm S/S Blade electrode, 3m cable, 3m tubing       |
| PS17-K3XGY   | PS17 Smoke evacuation Handpiece, 70mm+100mm+152mm Non-stick Blade electrode, 3m cable, 3m tubing |
| 12-02  | PS17 Smoke evacuation Handpiece, 70mm Non-stick Blade electrode, 5m cable, 3m tubing             |
| PS17-G01   | PS17 Smoke evacuation Handpiece, 35mm nozzle, 3m cable, 3m tubing                                |
| PS17-G02   | PS17 Smoke evacuation Handpiece, 83mm nozzle, 3m cable, 3m tubing                                |
| PS09-K50   | Telescopic Smoke evacuation Handpiece, 50mm S/S Blade electrode, 3m cable, 3m tubing             |
| PS09-K50L  | Telescopic Smoke evacuation Handpiece, 50mm S/S Blade electrode, 5m cable, 3m tubing             |
| PS09-K50L2   | Telescopic Smoke evacuation Handpiece, 50mm S/S Blade electrode, 5m cable, 4.5m tubing           |
| PS09-K50GY   | Telescopic Smoke evacuation Handpiece, 50mm Non-stick Blade electrode, 3m cable, 3m tubing       |
| PS09-K55GY   | Telescopic Smoke evacuation Handpiece, 55mm Non-stick Blade electrode, 3m cable, 3m tubing       |
| PS09-K50GYL  | Telescopic Smoke evacuation Handpiece, 50mm Non-stick Blade electrode, 5m cable, 3m tubing       |
| PS09-K55GYL  | Telescopic Smoke evacuation Handpiece, 55mm Non-stick Blade electrode, 5m cable, 3m tubing       |
| PS09-K50GYL2   | Telescopic Smoke evacuation Handpiece, 50mm Non-stick Blade electrode, 5m cable, 4.5m tubing     |
| PS11-K50   | Telescopic Smoke evacuation Handpiece, 50mm S/S Blade electrode, 3m cable, 3m tubing             |
| PS11-K50L  | Telescopic Smoke evacuation Handpiece, 50mm S/S Blade electrode, 5m cable, 3m tubing             |
| PS11-K50L2   | Telescopic Smoke evacuation Handpiece, 50mm S/S Blade electrode, 5m cable, 4.5m tubing           |
| PS11-K50GY   | Telescopic Smoke evacuation Handpiece, 50mm Non-stick Blade electrode, 3m cable, 3m tubing       |
| PS11-K55GY   | Telescopic Smoke evacuation Handpiece, 55mm Non-stick Blade electrode, 3m cable, 3m tubing       |
| PS11-K50GYL  | Telescopic Smoke evacuation Handpiece, 50mm Non-stick Blade electrode, 5m cable, 3m tubing       |
| PS11-K55GYL  | Telescopic Smoke evacuation Handpiece, 55mm Non-stick Blade electrode, 5m cable, 3m tubing       |
| PS11-K50GYL2   | Telescopic Smoke evacuation Handpiece, 50mm Non-stick Blade electrode, 5m cable, 4.5m tubing     |
| PS18-K50   | Telescopic Smoke evacuation Handpiece, 50mm S/S Blade electrode, 3m cable, 3m tubing             |
| PS18-K50L  | Telescopic Smoke evacuation Handpiece, 50mm S/S Blade electrode, 5m cable, 3m tubing             |
| PS18-K50L2   | Telescopic Smoke evacuation Handpiece, 50mm S/S Blade electrode, 5m cable, 4.5m tubing           |
| PS18-K50GY   | Telescopic Smoke evacuation Handpiece, 50mm Non-stick Blade electrode, 3m cable, 3m tubing       |
| PS18-K55GY   | Telescopic Smoke evacuation Handpiece, 55mm Non-stick Blade electrode, 3m cable, 3m tubing       |
| PS18-K50GYL  | Telescopic Smoke evacuation Handpiece, 50mm Non-stick Blade electrode, 5m cable, 3m tubing       |
| PS18-K55GYL  | Telescopic Smoke evacuation Handpiece, 55mm Non-stick Blade electrode, 5m cable, 3m tubing       |
| PS18-K50GYL2   | Telescopic Smoke evacuation Handpiece, 50mm Non-stick Blade electrode, 5m cable, 4.5m tubing     |
| PS28-K63   | Smoke evacuation Handpiece, 63mm S/S Blade electrode, 3m cable, 3m tubing                        |
| PS28-K63L  | Smoke evacuation Handpiece, 63mm S/S Blade electrode, 5m cable, 3m tubing                        |
| PS28-K63L2   | Smoke evacuation Handpiece, 63mm S/S Blade electrode, 5m cable, 4.5m tubing                      |
| PS28-K63GY   | Smoke evacuation Handpiece, 63mm Non-stick Blade electrode, 3m cable, 3m tubing                  |
| PS28-K70GY   | Smoke evacuation Handpiece, 70mm Non-stick Blade electrode, 3m cable, 3m tubing                  |
| PS28-K63GYL  | Smoke evacuation Handpiece, 63mm Non-stick Blade electrode, 5m cable, 3m tubing                  |
| PS28-K70GYL  | Smoke evacuation Handpiece, 70mm Non-stick Blade electrode, 5m cable, 3m tubing                  |
| PS28-K63GYL2   | Smoke evacuation Handpiece, 63mm Non-stick Blade electrode, 5m cable, 4.5m tubing                |
| 12-01  | Smoke evacuation Handpiece, 63mm Non-stick Blade electrode, 5m cable, 3.5m tubing                |
| 20321-060  | Smoke evacuation Handpiece, 63mm Non-stick Blade electrode, 5m cable, 3.5m tubing                |

**Annex I, Part2**  
**Accessories for Smoke Evacuation Pencil**

Including non-sterile supplied products with "-NS" attached to the REF

|          |   |
|----------|---|
| ESE-TS1  | Gynecological smoke evacuation tubing with filter,3 meters,1/4 (6.4mm) speculum connection,7/8 in (22 mm) smoke evacuation connection                                 |
| ESE-TS2  | 1.8 meters 7/8 in (22 mm) smoke evacuation tubing with 0.6 meter 1/4 (6.4mm) tubing   |
| ESE-TS3  | Laparoscopic smoke evacuation tubing,3 meters,luer connection,7/8 in (22 mm) connector  |
| ESE-TS4  | Laparoscopic smoke evacuation tubing with suction regulator,3 meters,luer connection,7/8 in (22 mm) connector   |
| 12-LS-01 | Laparoscopic smoke evacuation tubing with suction regulator,3 meters,luer connection,7/8 in (22 mm) connector   |
| ESE-TS5  | Laparoscopic smoke evacuation tubing,3 meters,luer connection,7/8 in (22 mm) connector  |
| ESE-TS6  | 3 meters 7/8 in (22 mm) smoke evacuation tubing with sponge guard,sterile   |
| ESE-TS7  | 3 meters 7/8 in (22 mm) smoke evacuation tubing with sponge guard,non-sterile   |
| ESE-TS8  | 1.8 meters 7/8 in (22 mm) smoke evacuation tubing with sponge guard,sterile   |
| ESE-TS9  | 1.8 meters 7/8 in (22 mm) smoke evacuation tubing with sponge guard,non-sterile   |
| ESE-CN1  | Large PreFilter to 10mm Connector   |
| ESE-CN2  | 22mm Female x 10mm Male Straight Connector  |
| ESE-CN3  | 10mm Male x 10mm Male Connector   |
| ESE-CN4  | 22mm male/male connector  |
| ESE-CN5  | Smoke evacuation 10mm adaptor   |
| ESE-CN6  | 22mm Female x 10mm Male Straight Connector,with Suction Canister Port   |
| ESE-CN7  | Smoke evacuation Y adaptor,22mm   |
| ESE-CN8  | Smoke evacuation 22mm adaptor   |
| P-F1     | Disposable Smoke Evacuation HEPA Filter kit with fluid trap,22mm male entrance,22mm female/male exit,compatible with suction canister,BFE>99.99% VFE>99.99%           |
| P-F2     | Disposable Smoke Evacuation HEPA Filter kit with fluid trap,22mm male entrance,22mm female/male exit,compatible with 1/4"-3/8" suction canister,BFE>99.99% VFE>99.99% |
| P-F3     | Disposable Smoke Evacuation HEPA Filter kit with fluid trap,22mm male entrance,22mm female exit,BFE>99.99% VFE>99.99%   |
| P-F4     | 22mm male/male HEPA filter  |
| P-FT1    | Smoke evacuation Liquid Trap,22mm connection 50ml   |
| P-FT2    | Smoke evacuation Liquid Trap,22mm connection 120ml  |
| 12-VF-01 | Smoke evacuation Liquid Trap,22mm connection 50ml   |
| 12-VF-02 | Smoke evacuation Liquid Trap,22mm connection 120ml  |

浙江迈德实达医疗科技有限公司  
ZHEJIANG MEDSTAR TECHNOLOGY CO.,LTD.