# EC DECLARATIONOF CONFORMITY

According toMDD 93/42/EEC, amended by 2007/47/EC

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|---|---|
| **Manufacturer:** | Shangxian Minimal Invasive Inc.<br>1st Floor, Block B2-2, China medicine innovation park, Mulan road, Hi-tech development zone, 117004 Benxi, Liaoning, China |
| **EuropeanRepresentative:** | MedPath GmbH<br>Mies-van-der-Rohe-Strasse8<br>80807 Munich, Germany |
| **Product name:** | **Disposable Grasping Forceps** |
| **Product code / Catalogue number:** | UMDNS-CODE/Preferred Terms: 11775<br>Model:<br>MI-FG-TY(ZJ/3ZX/4ZX/5ZX)-18(23)*800(1200/1600/1800/2300/2500);<br>MI-FG-CXDZ-18(23)*800(1200/1600/2300/2500). |
| **Classification acc. to MDD Ax. IX:** | Class IIa, rule 7 |
| **Applied Standards:** | EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-10:2010, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, EN ISO 11737-2:2020, ISO 11135:2014, MEDDEV. 2.7.1 Rev.4, MEDDEV 2.12/2, ASTM D4169-2016 |
| **Conformity assessment procedure:** | MDD Annex II (without II.4) |
| **CE certificate No.:** | HD 2114740-1 |
| **Name and ID of the Notified Body:** | TÜV Rheinland LGA Products GmbH<br>CE0197 |

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Directive 93/42/EEC on Medical Devices (MDD), amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

*For and on behalf of*

沈阳尚贤医疗系统有限公司

SHANGXIAN MINIMAL INVASIVE INC.

Shenyang, Jan. 22th, 2022

Signature: Li Yuxia

General Manager

Digitally signed by Rusu Cristina
Date: 2023.10.29 17:30:53 EET
Reason: MoldSign Signature
Location: Moldova

*Authorized signature(s)*