TIANCK MEDICAL CO., LTD.
ADD:1-2 Floor, Building C, No.16 Yinkui road, Kuichong town, Dapeng new district, Shenzhen, 518119 Guangdong P.R. China
TEL: +86 755 28395385 FAX: +86 755 28397620
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天可医疗 Tianck Medical

CÔNG TY CỔ PHẦN NOVAMED VIỆT NAM

CE

# Declaration of Conformity

CE

**Product Name:** Balloon inflation devices

**Medical Device Directive:** In compliance with Directive 93/42/EEC, as amended by directive 2007/47/EEC

**Authorized Representative:** Lotus NL B.V.
**Address:** Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
**Manufacturer:** Tianck Medical Co.,Ltd
**Address:** 1-2 Floor, Building C, No.16 Yinkui road, Kuichong town, Dapeng new district, Shenzhen, 518119 Guangdong P.R. China

**Specification/Models:** Respect to CE Technical File TK-MDTF-BID

**Classification:** Class I (MD 0106)

**Standards:**

| | |
|---|---|
| YY/T 0450.3-2016 | ISO 11607-1: 2019 |
| ISO 10993-1:2018 | ISO 11607-2: 2019 |
| ISO 10993-4:2002/Amd.1:2006(E) | ISO 15223-1:2016 |
| ISO 10993-5:2009 | ISO 20417:2021 |
| ISO 10993-7:2008 | ISO 13485:2016 |
| ISO 10993-10:2010 | ISO 11135:2014 |
| ISO 10993-11:2016 | ISO 14971:2019 |
| EN 62366-1:2015 | |

**All applicable harmonized standards (published in the Official Journal of the European communities)**

**Conformity assessment modules:** Directive 93/42/EEC Annex II

**Certificate Register No.:** HD 2139971-1

**Signature:**

**Stamper:**

**Date:2023/03/08**

**Notified Body:**
TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

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天可医疗 Tianck Medical

# Certificate of Analysis

Product name: Balloon inflation devices

Model: BID2

Batch number: TK624145A

Manufacture date: 2024.04.05

Expiry date: 2027.04.04

Tests performed

| Test | Acceptance criteria | Result |
|---|---|---|
| Physical performance | Units of measurement; Zero point; Indicator value resolution; Negative pressure indication; Basic error; Repeatability; Hysteresis error; Stability; Indication value fluctuation; Safety requirements; Positive pressure tightness; Pressure release; Hemostasis valve sets(Appearance, Size, Insertion tool (rigidity, toughness, corrosion resistance), Sealing, Conical connector, Coordination, Particulate contamination, Connection strength); Negative pressure retention; Pressure decay; Operational reliability of the release device; Direction of rotation; Bubble observation and elimination; Extension Tube Dimensions; Volume scale; Capacity tolerance; Conical joint | Pass |
| Chemical performance | pH value ≤1.0<br>Reduction material ≤0.5ml<br>Heavy metal ≤5.0 μg/ml (except for cadmium, cadmium < 0.1 μg/mL)<br>Ethylene oxide residue ≤10.0μg/g | Pass |
| Biological performance | Sterile<br>Bacterial endotoxin ≤0.5EU/ML | Pass |
| Visual inspection | The product does not contain particles. | Pass |

The sterilization process used the EO sterilization method and complies with the EN ISO 11135 and other relevant standards and has a sterility certificate.

Approved by: Gao Dan

Signature: Gao Dan

Position: QC Manager

Issued on(Date): 20 April, 2024

TIANCK MEDICAL CO., LTD. 品质专用章 QC PASS

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天可医疗 Tianck Medical

# Certificate of Analysis

Product name: Balloon inflation devices

Model: BID1

Batch number: TK624145A

Manufacture date: 2024.04.05

Expiry date: 2027.04.04

Tests performed

| Test | Acceptance criteria | Result |
|---|---|---|
| Physical performance | Units of measurement; Zero point; Indicator value resolution; Negative pressure indication; Basic error; Repeatability; Hysteresis error; Stability; Indication value fluctuation; Safety requirements; Positive pressure tightness; Pressure release; Hemostasis valve sets(Appearance, Size, Insertion tool (rigidity, toughness, corrosion resistance), Sealing, Conical connector, Coordination, Particulate contamination, Connection strength); Negative pressure retention; Pressure decay; Operational reliability of the release device; Direction of rotation; Bubble observation and elimination; Extension Tube Dimensions; Volume scale; Capacity tolerance; Conical joint | Pass |
| Chemical performance | pH value ≤1.0<br>Reduction material ≤0.5ml<br>Heavy metal ≤5.0 μg/ml (except for cadmium, cadmium < 0.1 μg/mL)<br>Ethylene oxide residue ≤10.0μg/g | Pass |
| Biological performance | Sterile<br>Bacterial endotoxin ≤0.5EU/ML | Pass |
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