

# EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Nanchang Kanghua Health Materials Co., Ltd.**  
Moonlight Road, Medical Device Technology Park, Jinxian,  
Nanchang, Jiangxi 331700, China

EC Authorized Representative: **MedPath GmbH**  
Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

We declare under our sole responsibility that  
the medical device: **Urethral Catheters for single use**  
Brand Name: **CHENKANG**

No.	Products	Models	UMDNS Code	Classification Rules	Classification
1	Urethral Catheters for single use	1-way Spec:Fr6, Fr8, Fr10, Fr12, Fr14, Fr16, Fr18, Fr20, Fr22, Fr24, Fr26,	14292	Rule 5 (2.1.4)	IIb
2	Urethral Catheters for single use	2-way Spec:Fr6, Fr8, Fr10, Fr12, Fr14, Fr16, Fr18, Fr20, Fr22, Fr24, Fr26,	14292	Rule 5 (2.1.4)	IIb
3	Urethral Catheters for single use	3-way Spec: Fr16, Fr18, Fr20, Fr22, Fr24, Fr26,	14292	Rule 5 (2.1.4)	IIb

according to annex IX of directive 93/42/EEC / **Rule 5 (2.1.4)**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Conformity assessment procedure: / **Directive 93/42/EEC Annex V.**

Registration No.: **HD60145250 0001**

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

Applicable Standards

EN 556-1:2001/ AC:2006, EN 1782:1998+A1:2009, EN 1041:2008, ASTM F1980-07, ASTM F1980-07, EN ISO 10993- 1:2009/AC:2010, EN ISO 10993-5:2009, ISO 10993-7:2008, EN ISO 10993- 10:2013, EN ISO 10993- 12:2012, ISO 11135:2014, ISO 11607- 1:2006/Amd 1:2014, ISO 11607- 2:2006/Amd 1:2014, EN ISO 11737- 1:2006/AC:2009, EN ISO 11737- 2:2009, EN ISO 14644-1:2015, ISO 14644-2:2015, EN ISO 14644-8:2006, ISO 14698-1:2003, ISO 14698- 2:2003/Cor 1:2004, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 62366:2008, MEDDEV 2.7/1, rev. 4: 2016

Jinxian, Jiangxi, 22.03.2023  
Place (地址), date (日期)

朱艳霞 Zhu Yanxia QMR  
Name (姓名) and function (职务)  
**南昌市康华卫材有限公司**  
**NANCHANG KANGHUA HEALTH MATERIALS CO.,LTD**

**姜义堂**