EC Declaration of Conformity

Name and address of the manufacturer:	**Hangzhou Jimushi Meditech Co., Ltd.** **Building 1, No.12 Longtan Road, Cangqian Street, Yuhang District, 311121 Hangzhou, China**
Name and address of the European Authorized Representative:	**Shanghai International Holding Corp.GmbH(Europe)** **Eiffestraβe 80, 20537 Hamburg Germany.** **Tel:0049-40-2513175 Fax:0049-40-255726**
Notifying body:	**DEKRA Certification B.V.** **Meander 1051 6825 MJ Arnhem, Netherland**
Notified Body number:	**0344**
Certificate No.:	**6061308CE01**
Expiry date of the certificate:	**26, May, 2024**
We declare under our sole responsibility that the medical device:	**Sterile urethral catheter for single use**
UMDNS-code:	**10734**
UMDNS description (Device group):	**Catheters, Nelaton**
Product specification:	**Common type, hydrophilic coated type, hydrophilic coated with water pocket type, hydrophilic coated ready to use.** **Specifications: Nelaton tip, Tiemann tip** **08Fr,10Fr,12Fr,14Fr,16Fr,18Fr.** **For male, for female and for pediatric use.** **Catalogue Numbers:** NC08M, NC10M, NC12M, NC14M, NC16M, NC18M, NC08MC, NC10MC, NC12MC, NC14MC, NC16MC, NC18MC, NC08F, NC10F, NC12F, NC14F, NC16F, NC18F, NC08P, NC10P, NC12P, NC14P, NC16P, NC18P; NCH08M, NCH10M, NCH12M, NCH14M, NCH16M, NCH18M, NCH08MC, NCH10MC, NCH12MC, NCH14MC, NCH16MC, NCH18MC, NCH08F, NCH10F, NCH12F, NCH14F, NCH16F, NCH18F, NCH08P, NCH10P, NCH12P, NCH14P, NCH16P, NCH18P; NCW08M, NCW10M, NCW12M, NCW14M, NCW16M, NCW18M, NCW08MC, NCW10MC, NCW12MC, NCW14MC, NCW16MC, NCW18MC, NCW08F, NCW10F, NCW12F, NCW14F, NCW16F, NCW18F, NCW08P, NCW10P, NCW12P, NCW14P, NCW16P, NCW18P, NCR08M, NCR10M, NCR12M, NCR14M, NCR16M, NCR18M, NCR08MC, NCR10MC, NCR12MC, NCR14MC, NCR16MC, NCR18MC, NCR08F, NCR10F, NCR12F, NCR14F, NCR16F, NCR18F, NCR08P, NCR10P, NCR12P, NCR14P, NCR16P, NCR18P
of class:	**Class IIa**
according to annex IX of directive 93/42/EEC:	**Rule 5**

EC Declaration of Conformity

with CE mark 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. All products meet the intend use. All supporting documentation are retained under the premise of manufacturer.
The manufacturer is exclusively responsible for the declaration of conformity.

The above-mentioned medical device is applicable to: **ISO 20696:2018(E) Sterile urethral catheters for single use**

Conformity assessment procedure: **Directive 93/42/EEC, Annex II excluding section 4.**

Hangzhou, Oct. 27, 2020
Place and date

Wu fenlong
Mr. Wu Fenlong/Quality Management Representative

Appendix

LEIV-H	**CARECATH Leiv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig verpackt CH12-16 Nelatonspitze Länge:41cm 1VE:30Stück**
LEIV-H1241	CARECATH Leiv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig verpackt CH12 Nelatonspitze Länge:41cm 1VE:30Stück
LEIV-H1441	CARECATH Leiv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig verpackt CH14 Nelatonspitze Länge:41cm 1VE:30Stück
LEIV-H1641	CARECATH Leiv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig verpackt CH16 Nelatonspitze Länge:41cm 1VE:30Stück
LIV-H	**CARECATH Liv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig CH06-16 Nelatonspitze Länge:15cm 1VE:30Stück**
LIV-H0617	CARECATH Liv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig CH06 Nelatonspitze Länge:17cm 1VE:30Stück
LIV-H0817	CARECATH Liv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig CH08 Nelatonspitze Länge:17cm 1VE:30Stück
LIV-H1017	CARECATH Liv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig CH10 Nelatonspitze Länge:17cm 1VE:30Stück
LIV-H1217	CARECATH Liv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig CH12 Nelatonspitze Länge:17cm 1VE:30Stück
LIV-H1417	CARECATH Liv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig CH14 Nelatonspitze Länge:17cm 1VE:30Stück
LIV-H1617	CARECATH Liv Hydrophiler ISK Einmalkatheter sofort gebrauchsfertig CH16 Nelatonspitze Länge:17cm 1VE:30Stück