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Document Nr.: WL-MDR-DOC-016-01-07/A

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, People's Republic of China
SRN:	CN-MF-000006728
European Representative:	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestrasse 80, 20537 Hamburg, GERMANY
SRN:	DE-AR-000000001
Product Name:	Suction Catheter
Intended Purpose:	Suction Catheter is used to suck the sputum and secretion in respiratory tract, in order to prevent plugging of the airways. The catheter is used by directly inserted into the throat or through inner lumen of Tracheal Tube.
Type/ Size/ Catalogue Number:	Please refer to Table 1
GMDN Code:	10749
EMDN Code:	A06010103
Basic UDI-DI:	Please refer to Table 1

Classification (MDR, Annex Ⅷ): **IIa, Rule 5**

Conformity Assessment Route: Quality Management System (Annex IX, Chapter I & III and section 4) + Declaration of Conformity (Annex IV)

We herewith declare in our sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer. The declaration of conformity is issued under our sole responsibility.

Regulation(s)

General applicable regulations: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applicable Standard(s):
ISO 8836-2019/ ISO 18190:2016/ EN ISO 13485:2016+A11:2021/ EN ISO 14971:2019/ CEN ISO/TR 24971:2020/ EN ISO 20417:2021/ EN ISO 14644-1:2015/ EN ISO 14644-2:2015/ EN ISO 14644-3:2019/ EN ISO 14644-4:2022/ EN ISO 14644-5:2004/ EN ISO 14644-7:2004/ EN ISO 14644-8:2022/ EN ISO 14644-9:2022/ EN ISO 14644-10:2022/ ISO 14644-12:2018/ EN ISO 14644-13:2017/ EN ISO 14644-14:2016/ EN ISO 14644-15:2017/ EN ISO 14644-16:2019/ EN ISO 14644-17:2021/ EN ISO 11135:2014+A1:2019/ EN ISO 11737-1:2018+A1:2021/ EN ISO 11737-2:2020/ EN ISO 11138-1:2017/ EN ISO 11138-2:2017/ EN ISO 15223-1:2021/ EN ISO 10993-1:2020/ EN ISO 10993-5:2009/ EN ISO 10993-10:2013/ ISO/TS 21726:2019/ IEC 62366-1:2015+AMD1:2020/ IEC/TR 62366-2:2016/ ISTA 2A /EN 15986:2011/ CEN ISO/ EN 556-1:2001+AC:2006/ EN 556-2:2015/ EN 868-2:2017/ ASTM F1929-15/ ASTM F88-15/ ASTM F1886-16/ EN ISO 11607-1:2020+A11:2022/ EN ISO 11607-2:2020+A11:2022/ ASTM F1980-21/ MDCG 2020-5/ MDCG 2020-6/ MEDDEV 2.7.1 rev.4/ MEDDEV 2.12-1 rev.8/ MEDDEV 2.12-2 rev.2/ MDCG 2020-7/ MDCG 2020-8/ SCHEER guidelines/ MDCG 2018-1 rev.4/ MDCG 2019-1

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Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	G10 038814 0092 Rev. 01
Expire date of the Certificate:	2028/5/15
Start of MDR CE Marking:	2023/12/12

Signature:



Name: Chen Yun Gui

Position: **Management Representative & PRRC**

Place, Date of Issue: **Guangzhou, 2024-09-14**

Add: C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
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Table1

Model	Type	Basic UDI-DI	UNOQUIP REF Number	Product Description
Straight	Mully, Y-Type transparent connector	69449327FN02A00HE	12500118	Suction Catheter Mülly, 33cm, straight, Vacutip, Std-Hardness, METRIC CH5
			12500318	Suction Catheter Mülly, 33cm, straight, Vacutip, Std-Hardness, METRIC CH7
			70000338	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, METRIC CH7
			70000138	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, METRIC CH5
			70000348	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, METRIC CH7
			70000218	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, METRIC CH6
			70000418	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, METRIC CH8
			70000518	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, METRIC CH10
			70000618	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, METRIC CH12
			70000718	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, METRIC CH14
			70000818	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, METRIC CH16
			70000228	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, METRIC CH6
			70000428	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, METRIC CH8
			70000928	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, METRIC CH10
			70001028	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, METRIC CH12
			70001128	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, METRIC CH14
			70001228	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, METRIC CH16
			70001328	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, METRIC CH18
			71000218	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, NO metric, CH6
			71000418	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, NO metric, CH8
			71000518	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, NO metric, CH10
			71000618	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, NO metric, CH12
			71000718	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, NO metric, CH14
			71000818	Suction Catheter Mülly, 49cm, straight, Vacutip, Std-Hardness, NO metric, CH16
			71000428	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, NO metric, CH8
			71000928	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, NO metric, CH10
			71001028	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, NO metric, CH12

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Model	Type	Basic UDI-DI	UNOQUIP REF Number	Product Description
Straight	Mully, Y-Type transparent connector	69449327FN02A00HE	71001128	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, NO metric, CH14
			71001228	Suction Catheter Mülly, 57cm, straight, Vacutip, Std-Hardness, NO metric, CH16
			12500228	Suction Catheter Mülly, 33cm, straight, Vacutip, Std-Hardness, METRIC CH6
			12500428	Suction Catheter Mülly, 33cm, straight, Vacutip, Std-Hardness, METRIC CH8
			12500528	Suction Catheter Mülly, 33cm, straight, Vacutip, Std-Hardness, METRIC CH10
			12500628	Suction Catheter Mülly, 33cm, straight, Vacutip, Std-Hardness, METRIC CH12
			12500728	Suction Catheter Mülly, 33cm, straight, Vacutip, Std-Hardness, METRIC CH14
			12500828	Suction Catheter Mülly, 33cm, straight, Vacutip, Std-Hardness, METRIC CH16
	Mully, Cap-cone	69449327FN02A00HE	60100218	Suction Catheter Mülly, 49cm, straight, Capcon, Std-Hardness, CH6
			60100318	Suction Catheter Mülly, 49cm, straight, Capcon, Std-Hardness, CH8
			60100418	Suction Catheter Mülly, 49cm, straight, Capcon, Std-Hardness, CH10
			60100518	Suction Catheter Mülly, 49cm, straight, Capcon, Std-Hardness, CH12
			60100618	Suction Catheter Mülly, 49cm, straight, Capcon, Std-Hardness, CH14
			60100718	Suction Catheter Mülly, 49cm, straight, Capcon, Std-Hardness, CH16
			60100818	Suction Catheter Mülly, 49cm, straight, Capcon, Std-Hardness, CH18
	Mully, Funnel	69449327FN02A00HE	12000118	Suction Catheter Mülly, 33cm, straight, Funnel, Std-Hardness, METRIC CH4
			12000218	Suction Catheter Mülly, 33cm, straight, Funnel, Std-Hardness, METRIC CH5
			50000118	Suction Catheter Mülly, 49cm, straight, Funnel, Std-Hardness, METRIC, CH5
			50000218	Suction Catheter Mülly, 49cm, straight, Funnel, Std-Hardness, CH6
			50000318	Suction Catheter Mülly, 49cm, straight, Funnel, Std-Hardness, CH8
			50000418	Suction Catheter Mülly, 49cm, straight, Funnel, Std-Hardness, CH10
			50000518	Suction Catheter Mülly, 49cm, straight, Funnel, Std-Hardness, CH12
			50000618	Suction Catheter Mülly, 49cm, straight, Funnel, Std-Hardness, CH14
			50000718	Suction Catheter Mülly, 49cm, straight, Funnel, Std-Hardness, CH16
			50000818	Suction Catheter Mülly, 49cm, straight, Funnel, Std-Hardness, CH18
			50001028	Suction Catheter Mülly, 57cm, straight, Funnel, Std-Hardness, CH6
			50001128	Suction Catheter Mülly, 57cm, straight, Funnel, Std-Hardness, CH8

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Model	Type	Basic UDI-DI	UNOQUIP REF Number	Product Description
Straight	Mully, Funnel	69449327FN02A00HE	50001228	Suction Catheter Mülly, 57cm, straight, Funnel, Std-Hardness, CH10
			50001328	Suction Catheter Mülly, 57cm, straight, Funnel, Std-Hardness, CH12
			50001428	Suction Catheter Mülly, 57cm, straight, Funnel, Std-Hardness, CH14
			50001528	Suction Catheter Mülly, 57cm, straight, Funnel, Std-Hardness, CH16
			50001628	Suction Catheter Mülly, 57cm, straight, Funnel, Std-Hardness, CH18
			12000328	Suction Catheter Mülly, 33cm, straight, Funnel, Std-Hardness, METRIC CH6
			12000428	Suction Catheter Mülly, 33cm, straight, Funnel, Std-Hardness, METRIC CH8
			12000528	Suction Catheter Mülly, 33cm, straight, Funnel, Std-Hardness, METRIC CH10
			12000628	Suction Catheter Mülly, 33cm, straight, Funnel, Std-Hardness, METRIC CH12
			12000728	Suction Catheter Mülly, 33cm, straight, Funnel, Std-Hardness, METRIC CH14
			12000828	Suction Catheter Mülly, 33cm, straight, Funnel, Std-Hardness, METRIC CH16
			50020128	Suction Catheter Mülly, 21cm, straight, Funnel, Std-Hardness, CH12, Tracheostomy
			50020228	Suction Catheter Mülly, 21cm, straight, Funnel, Std-Hardness, CH14, Tracheostomy
	Mully, Elephant foot, Funnel	69449327FN02A00HE	25210118	Suction Catheter ATRAUMATIC, 21cm, straight, Funnel, Std-Hardness, METRIC, CH10
			25210218	Suction Catheter ATRAUMATIC, 21cm, straight, Funnel, Std-Hardness, METRIC, CH12
			25210318	Suction Catheter ATRAUMATIC, 21cm, straight, Funnel, Std-Hardness, METRIC, CH14
			25210418	Suction Catheter ATRAUMATIC, 21cm, straight, Funnel, Std-Hardness, METRIC, CH16
			25310118	Suction Catheter ATRAUMATIC, 57cm, straight, Funnel, Std-Hardness, METRIC, CH10
			25310218	Suction Catheter ATRAUMATIC, 57cm, straight, Funnel, Std-Hardness, METRIC, CH12
			25310318	Suction Catheter ATRAUMATIC, 57cm, straight, Funnel, Std-Hardness, METRIC, CH14
			25310418	Suction Catheter ATRAUMATIC, 57cm, straight, Funnel, Std-Hardness, METRIC, CH16
	Mully, Elephant foot, Y-Type transparent connector	69449327FN02A00HE	25410118	Suction Catheter ATRAUMATIC, 57cm, straight, Vacutip, Std-Hardness, METRIC, CH10
			25410218	Suction Catheter ATRAUMATIC, 57cm, straight, Vacutip, Std-Hardness, METRIC, CH12

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Model	Type	Basic UDI-DI	UNOQUIP REF Number	Product Description
Straight	Mully, Elephant foot, Y-Type transparent connector	69449327FN02A00HE	25410318	Suction Catheter ATRAUMATIC, 57cm, straight, Vacutip, Std-Hardness, METRIC, CH14
			25410418	Suction Catheter ATRAUMATIC, 57cm, straight, Vacutip, Std-Hardness, METRIC, CH16
	Mully, Y-Type transparent connector, soft	69449327FN02A01HG	70400118	Suction Catheter Mülly, 49cm, straight, Vacutip, SOFT, METRIC CH10
			70400218	Suction Catheter Mülly, 49cm, straight, Vacutip, SOFT, METRIC CH12
			70400318	Suction Catheter Mülly, 49cm, straight, Vacutip, SOFT, METRIC CH14
			70400418	Suction Catheter Mülly, 49cm, straight, Vacutip, SOFT, METRIC CH16
			70400518	Suction Catheter Mülly, 49cm, straight, Vacutip, SOFT, METRIC CH18
			70400628	Suction Catheter Mülly, 57cm, straight, Vacutip, SOFT, METRIC CH10
			70400728	Suction Catheter Mülly, 57cm, straight, Vacutip, SOFT, METRIC CH12
			70400828	Suction Catheter Mülly, 57cm, straight, Vacutip, SOFT, METRIC CH14
			70400928	Suction Catheter Mülly, 57cm, straight, Vacutip, SOFT, METRIC CH16
			70401028	Suction Catheter Mülly, 57cm, straight, Vacutip, SOFT, METRIC CH18
	Mully, Funnel, soft	69449327FN02A01HG	50100118	Suction Catheter Mülly, 49cm, straight, Funnel, SOFT, CH10
			50100218	Suction Catheter Mülly, 49cm, straight, Funnel, SOFT, CH12
			50100318	Suction Catheter Mülly, 49cm, straight, Funnel, SOFT, CH14
			50100418	Suction Catheter Mülly, 49cm, straight, Funnel, SOFT, CH16
			50100628	Suction Catheter Mülly, 57cm, straight, Funnel, SOFT, CH10
			50100728	Suction Catheter Mülly, 57cm, straight, Funnel, SOFT, CH12
			50100828	Suction Catheter Mülly, 57cm, straight, Funnel, SOFT, CH14
			50100928	Suction Catheter Mülly, 57cm, straight, Funnel, SOFT, CH16
			50101028	Suction Catheter Mülly, 57cm, straight, Funnel, SOFT, CH18
			12400128	Suction Catheter Mülly, 33cm, straight, Funnel, SOFT, METRIC CH10
			12400228	Suction Catheter Mülly, 33cm, straight, Funnel, SOFT, METRIC CH12
			12400328	Suction Catheter Mülly, 33cm, straight, Funnel, SOFT, METRIC CH14
			12400428	Suction Catheter Mülly, 33cm, straight, Funnel, SOFT, METRIC CH16
Curved tip	Mully, Y-Type transparent connector	69449327FN02A00HE	90000128	Suction Catheter Mülly, 57cm, curved, Vacutip, Std-Hardness, CH6
			90000228	Suction Catheter Mülly, 57cm, curved, Vacutip, Std-Hardness, CH8

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Model	Type	Basic UDI-DI	UNOQUIP REF Number	Product Description
Curved tip	Mully, Y-Type transparent connector	69449327FN02A00HE	90000328	Suction Catheter Mülly, 57cm, curved, Vacutip, Std-Hardness, CH10
			90000428	Suction Catheter Mülly, 57cm, curved, Vacutip, Std-Hardness, CH12
			90000528	Suction Catheter Mülly, 57cm, curved, Vacutip, Std-Hardness, CH14
			90000628	Suction Catheter Mülly, 57cm, curved, Vacutip, Std-Hardness, CH16
	Mully, Funnel	69449327FN02A00HE	80000118	Suction Catheter Mülly, 50cm, curved, Funnel, Std-Hardness, CH8
			80000218	Suction Catheter Mülly, 50cm, curved, Funnel, Std-Hardness, CH10
			80000318	Suction Catheter Mülly, 50cm, curved, Funnel, Std-Hardness, CH12
			80000418	Suction Catheter Mülly, 50cm, curved, Funnel, Std-Hardness, CH14
			80000518	Suction Catheter Mülly, 50cm, curved, Funnel, Std-Hardness, CH16
			80000618	Suction Catheter Mülly, 50cm, curved, Funnel, Std-Hardness, CH18
			80000728	Suction Catheter Mülly, 57cm, curved, Funnel, Std-Hardness, CH10
			80000828	Suction Catheter Mülly, 57cm, curved, Funnel, Std-Hardness, CH12
			80000928	Suction Catheter Mülly, 57cm, curved, Funnel, Std-Hardness, CH14
			80001028	Suction Catheter Mülly, 57cm, curved, Funnel, Std-Hardness, CH16
			80001128	Suction Catheter Mülly, 57cm, curved, Funnel, Std-Hardness, CH18
	Mully, Elephant foot, Funnel	69449327FN02A00HE	25510218	Suction Catheter ATRAUMATIC, 57cm, curved, Funnel, Std-Hardness, METRIC, CH12
			25510318	Suction Catheter ATRAUMATIC, 57cm, curved, Funnel, Std-Hardness, METRIC, CH14
	Mully, Funnel, Soft	69449327FN02A01HG	80200728	Suction Catheter Mülly, 57cm, curved, Funnel, SOFT, CH10
			80200828	Suction Catheter Mülly, 57cm, curved, Funnel, SOFT, CH12
			80200928	Suction Catheter Mülly, 57cm, curved, Funnel, SOFT, CH14
			80201028	Suction Catheter Mülly, 57cm, curved, Funnel, SOFT, CH16

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