EC Declaration of Conformity

Manufacturer:

Dongguan QueenMed Equipment Mfg. Co, Ltd.
Room 201, Building 1, No.18, Caole Industrial No.1 Road, Xiegang Town, Dongguan City, Guangdong, China,523592

EC Representative:

Umedwings Netherlands B.V.
Treubstraat 1,2288EG,Rijswijk, The Netherlands

We, the manufacturer, herewith declare that the products

Electrosurgical Pencils (sterile)

Specifications / Models: see attachment（EMDN code: K0201010）

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to **Class IIb** according to Annex IX, Rule 9 of the Directive 93/42/EEC. The conformity assessment route follows Annex II except Section 4 (EC declaration) of Directive 93/42/EEC. It bears the mark

CE 0482

The product concerned has been manufactured under a quality management system according to **Annex II without section 4** of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body with certificate No. 7032GB410200527.

MEDCERT GmbH

Pilatuspool 2, 20355 Hamburg, Germany

Following the procedure relating to the EC Declaration of Conformity set out in Anne II without section 4 of Directive 93/42/EEC.

Applied Standards:

EN ISO14971:2012, EN 1041:2008+A1:2013, EN ISO15223-1:2016, EN ISO13485: 2016, EN 60601-1:2014, EN 60601-1-2:2015, EN 60601-2-2:2018, ISO10993-2:2006, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ISO14155:2011, ISO17664:2017, ISO11137:2015, ISO11607-2:2006+A1:2014.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above-mentioned declaration of conformity is exclusively under the responsibility of

Dongguan QueenMed Equipment Mfg. Co, Ltd.
Room 201, Building 1, No.18, Caole Industrial No.1 Road, Xiegang Town, Dongguan City, Guangdong, China,523592

Dongguan City, june-17-2026 Kipson Fung, G.M

QS - 7032

Firmenname - Company Dongguan QueenMed Equipment Mfg Co., Ltd.

Datum - Date: 2021/5/10

cons. No. **Lfd. Nr.**	Product REF # **Produkt REF #**	Product Name **Produktname**	Class (MDD) **Klasse (MDD)**	Rule (MDD) **Regel (MDD)**	TF Name/Title **TF Name/Titel**	Revision **Revisionsstand**	Revision Date **Revisionsdatum**	Product Type **Produkttyp**	Reference to Scope of Certification **Refererenz zum Zertifikatsgeltungsbereich**	MD Code **MD Code**	EMDN Code **EMDN Code**	Sterile **Steril**	Type of Sterilization **Sterilisationsart**	In House Production **Eigenfertigung**
1	**SP200-P10S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
2	**SP200-R20S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
3	**SP200-F15S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
4	**SP200-B100S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
5	**SP200-B200S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
6	**SP200-B201S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
7	**SP200-RB230**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
8	**SP200-RB231**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
9	**SP200-B300S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
10	**SP200-C100S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
11	**SP200-C101S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
12	**SP200-C200S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
13	**SP200-C201S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
14	**SP200-C300S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
15	**SP200-C301S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
16	**SP200-N100S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
17	**SP200-N101S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
18	**SP200-N200S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
19	**SP200-N201S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
20	**SP200-N300S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
21	**SP200-E101S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
22	**SP200-E201S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
23	**SP200-E301S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
24	**SP200-L30S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
25	**SP200-L31S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
26	**SP200-L32S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
27	**SP200-L33S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
28	**SP200-L34S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
29	**SP200-L35S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
30	**SP200-L36S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
31	**SP200-L37S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes

32	**SP200-L38S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
33	**SP200-L39S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
34	**SP200-L40S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
35	**SP200-L41S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
36	**SP200-L42S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
37	**SP200-L43S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
38	**SP200-L44S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
39	**SP200-L45S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
40	**SP200-L46S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
41	**SP200-L47S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
42	**SP200-L48S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
43	**SP200-L60S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
44	**SP200-L61S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
45	**SP200-L62S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
46	**SP200-L63S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
47	**SP200-L64S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
48	**SP200-L65S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
49	**SP200-L69S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
50	**SP200-M70S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
51	**SP200-B76S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
52	**SP200-B77S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
53	**SP200-B78S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
54	**SP200-B79S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
55	**SP200-B80S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
56	**SP200-B81S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
57	**SP200-B82S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
58	**SP200-B83S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
59	**SP200-B84S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
60	**SP200-B85S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
61	**SP200-B86S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
62	**SP200-B87S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
63	**SP200-E94S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
64	**SP200-E95S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
65	**SP200-E96S**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
66	**ESPB4000Q**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
67	**ESPB4001Q**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
68	**ESPB4000LQ**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
69	**ESPB4001LQ**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
70	**ESPB4001ERBQ**	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes

ESRK4001Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
ESRK4001LQ	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
ESPB3001Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
ESPB4002Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
ESRK4002Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
ESRK4002LQ	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
SP200-C101Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
SP200-B202Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
SP200-B200Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
SP200-N200Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
SP200-N100Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
SP200-B100Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
ESPB4000BQ	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
ESPB4000BLQ	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
ESPB4001ERBLQ	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
ESFD3001Q	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2021/4/22	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
92646	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2021/4/22	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
92647	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2021/4/22	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
92648	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2021/4/22	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
92649	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2021/4/22	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes
SP200-P20S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2021/4/22	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	K0201010	Yes	Gamma	Yes