

EC Declaration of Conformity

Manufacturer:

Dongguan QueenMed Equipment Mfg Co., Ltd.
Building 1, Dongyuan Industrial Center, Xiajiao Village,
Caole Management Zone, Xiegang Town, Dongguan,
Guangdong – China

EC Representative:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany

We, the manufacturer, herewith declare that the products

Electrosurgical Pencils (sterile)

Specifications / Models: see attachment (GMDN code: 35030)

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



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 Annex 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.
Building 1, Dongyuan Industrial Center, Xiajiao Village,
Caole Management Zone, Xiegang Town, Dongguan,
Guangdong – China

Dongguan City, Oct- 15-2024

Kipson Fung, G.M

QS - 7032
Firmenname - Company Dongguan QueenMed Equipment Mfg Co., Ltd.
Datum - Date: 2024/10/15

cons. No.	Product REF #	Product Name	Class (MDD)	Rule (MDD)	TF Name/Title	Revision	Revision Date	Product Type	Reference to Scope of Certification	MD Code	GMDN Code	Sterile	Type of Sterilization	In House Production
Lfd. Nr.	Produkt REF #	Produktname	Klasse (MDD)	Regel (MDD)	TF Name/Titel	Revisionsstandard	Revisionsdatum	Produkttyp	Referenz zum Zertifikatsgeltungsbereich	MD Code	GMDN Code	Steril	Sterilisationsart	Eigenfertigung
1	SP200-P10S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
2	SP200-R20S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
3	SP200-F15S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical Pencil	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
4	SP200-B100S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
5	SP200-B200S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
6	SP200-B201S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
7	SP200-RB230	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
8	SP200-RB231	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
9	SP200-B300S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
10	SP200-C100S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
11	SP200-C101S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
12	SP200-C200S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
13	SP200-C201S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
14	SP200-C300S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
15	SP200-C301S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
16	SP200-N100S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
17	SP200-N101S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
18	SP200-N200S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
19	SP200-N201S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
20	SP200-N300S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
21	SP200-E101S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
22	SP200-E201S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
23	SP200-E301S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
24	SP200-L30S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
25	SP200-L31S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
26	SP200-L32S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
27	SP200-L33S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
28	SP200-L34S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
29	SP200-L35S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
30	SP200-L36S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes
31	SP200-L37S	Electrosurgical Pencil	IIb	Rule 9	TD 001	D	2020/10/14	electrosurgical loop electrode	Sterile Electrosurgical Pencil	1104	35030	Yes	Gamma	Yes

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